

## Ask a Patient Health News February 20, 2022

### Health News: February 20, 2022

- Safety labels were updated for **multiple sclerosis** drugs **Tecfidera** and **Vumerity**. Label changes include additional post-marketing adverse reactions for liver function abnormalities and alopecia (hair loss). Tecfidera has a 5,000 patient post-approval safety study requirement due to the FDA in October 2023.

[Tecfidera](#) label change

[Vumerity](#) label change

Tecfidera [patient reviews](#)

- **Robert Califf** was sworn in as the new Food and Drug Administration (FDA) Commissioner on February 17, 2022. Previously, Dr. Califf served as FDA Commissioner from February 2016 to January 2017.

<https://www.fda.gov/about-fda/fda-organization/robert-califf>

- The FDA warned consumers not to use certain powdered **infant formula** produced in Abbott Nutrition's facility in Sturgis, Michigan because of potential bacterial contamination, including salmonella. Do not use Similac, Alimentum, or EleCare powdered infant formulas if: the first two digits of the code are 22 through 37; and the code on the container contains K8, SH or Z2; and the expiration date is 4-1-2022 (APR 2022) or later.

[FDA Press Release on Recall](#)

### Diabetes, Weight Loss and Mental Health Apps in the News

- The FDA cleared the first smartphone-delivery system for initiating **insulin delivery**. The mobile app for android and iOS pairs with **Tandem Diabetes Care's d X2 insulin pump**, and discreetly displays a patient's pump information on a personal smartphone. This is a big plus for people who prefer not to have pumps out in public settings.

[FDA Press Release](#)

- **Noom** Inc. reached a \$62 million settlement in a lawsuit accusing the weight loss app provider of **tricking customers** into signing up for "risk-free" trial periods only to force them into automatic, costly renewals that extracted up to eight months of nonrefundable payments once its trial periods expired. Noom also made changes to its business practices that the company and the customers' lawyers valued at between \$31.2 million and \$120 million.

<https://www.reuters.com/legal/litigation/noom-diet-app-reaches-62-mln-settlement-over-automatic-subscription-renewals>

- How well does Noom work? BuzzFeed News writer Scaachi Koul was constantly targeted by ads for the app and so decided to investigate. "The dozens of women I spoke to about Noom had some version of this story: They joined the app to lose that last 10 pounds, or to work on their relationship with food, and were instead rattled by the weigh-ins and the tight calorie count. They also didn't find the **psychological element** that helpful. Most of the women were raised in some form of diet culture, meaning that they already knew some of Noom's tips — like taking a sip of water between bites to slow you down — and decided the app might not be worth \$60 a month."

<https://www.buzzfeednews.com/article/scaachikoul/noom-weight-loss-diet-app-men>

- Meta (Facebook) and TikTok [removed advertisements](#) from **Cerebral**, a mental health care startup valued at \$4.8 billion after receiving inquiries from NBC News. The social media platforms found the ads promoted negative body images and contained misleading health claims, such as linking ADHD to obesity. Cerebral recently hired Olympic gymnast **Simone Biles** as its "Chief Impact Officer." Like Noom, Cerebral has received **complaints about its subscriptions** service and sneaky pricing plans. The company charges \$85/month for the basic mental health service through an app and also offers online or phone therapy sessions with either "licensed clinicians" for an extra cost or unlicensed "care counselors." Consumers should make sure to read the fine print in any subscription-based app purchase before providing credit card numbers that are authorized for ongoing payments.

<https://www.forbes.com/sites/katiejennings/2022/02/18/getting-a-refund-from-mental-health-startup-cerebral-can-take-its-own-toll-on-customers/>

- Two CDC studies examined pediatric **emergency department** visit data from 2019 through January 2022. While the total number of visits decreased overall, the number and proportion of visits increased for certain types of injuries, chronic diseases, and behavioral health concerns. There was an alarming increase in visits among **adolescent females** for various mental health disorders, with visits for **eating disorders** doubling and those for **tic disorders** tripling between 2019 and January 2022. The studies were published in *MMWR*.

<https://www.cdc.gov/mmwr/volumes/71/wr/mm7108e2.htm>

<https://www.cdc.gov/mmwr/volumes/71/wr/mm7108e1.htm>

- At 73, actress and singer Olivia Newton-John is enduring her third bout with **breast cancer** since 1992. In 2017, she learned the disease had spread to her spine and was diagnosed with stage four breast cancer. *Prevention Magazine* describes how she is persisting thanks to two things: **optimism** and **cannabis**. In addition to setting up a cancer treatment facility in Australia, she and her husband set up a foundation in the U.S. that funds global research into **plant-based therapies** that treat and provide better quality of life for people with cancer.

<https://www.prevention.com/health/health-conditions/a39122778/olivia-newton-john-cannabis-cancer-treatment/>

- By a vote of 2-2, the Federal Trade Commission (FTC) rejected a proposal that would require an investigation into the business practices of the **Pharmacy Benefits Managers (PBM)** industry. This was a crushing blow to PBM critics, who have long advocated for a deep federal probe of these middlemen in the drug supply chain. Pharmacists' horror stories with PBMs flooded the hearing. None of the comments in the open hearing came from industry advocates, but the trade association Pharmaceutical Care Management Association (PCMA) announced it will soon launch a new ad campaign promoting how it helps pharmacies and patients. Although the revised description of the proposed FTC probe was a key reason for its rejection, the public is not allowed to see what was proposed unless it is approved by the commission, an FTC spokeswoman said.

More on the meeting:

<https://endpts.com/open-season-on-pbms-but-ftc-votes-against-digging-into-their-anti-competitive-practices-further/>

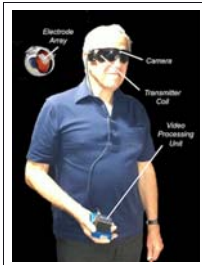
Report on the topic from [Columbus Dispatch](#)

- In 2021, **18 state governments** passed laws that attempt to regulate and improve the transparency of PBMs, although the laws are being challenged by industry every step of the way. Here's a summary of state-passed PBM legislation from 2021:

<https://www.natlawreview.com/article/pharmacy-benefit-managers-licensing-and-compliance-developments>

- Barbara Campbell was delighted with the **retinal implant** that gave her a crude kind of "bionic vision" that allowed her to see patches of light and dark. She had a genetic disease that had rendered her completely blind in her 30s. But the day her **Argus II retinal implant system** powered down, she heard it "beep beep beep" while she was transferring trains on a Manhattan subway, and it hasn't worked since, leaving her **completely blind** once more. The company behind the implants, **Second Sight Medical Products**, was going bankrupt and no longer supports the devices that had been implanted in the **eyes of around 350 people** worldwide. IEEE Spectrum's investigation reveals that the company took hundreds of patients on a roller-coaster ride of technological innovations, regulatory successes, medical and financial setbacks, and a near-total meltdown.

<https://spectrum.ieee.org/bionic-eye-obsolete>



The Argus II system has two separate components: a camera and visual processing unit that the patient wears and the surgically implanted receiving antenna and electrodes.

(Image Source: [Researchgate.net](https://www.researchgate.net))

- Researchers at Peking University's National Institute on Drug Dependence set out to estimate the **global prevalence** of various sub-types of **digital addiction**. Their meta-analysis included 495 articles with 504 studies covering 2,123,762 individuals from 64 countries. Global pooled prevalence estimates were **26.99% for smartphone addiction**, 17.42% for social media addiction, 14.22% for Internet addiction, 8.23% for cybersex addiction, and 6.04% for game addiction. Higher prevalence of digital addiction was found in Eastern Mediterranean region and low/lower-middle income countries. Males had higher risk for Internet and game addiction. An increasing trend of digital addiction during the past two decades was found, which dramatically worsened during COVID-19 pandemic. The study was published in *Clinical Psychology Review*.

<https://www.sciencedirect.com/science/article/abs/pii/S0272735822000137>

- A 23-year old woman with a long history of **mental illness** suddenly become combative and was deemed a threat to herself and others. Chloe was strapped down to a gurney and sent to an emergency room while waiting for admission to a psychiatric hospital. An emergency room doctor - with an astute gut instinct - ordered a **CT scan** of Chloe's head to better assess her mental status. The doctor was astonished not only at what the test revealed, but that such a test had never been done before. Check out Sandra Boodman's latest **medical mystery**.

<https://traviscountynewsonline.com/she-was-headed-to-a-locked-psych-ward-then-an-er-doctor-made-a-startling-discovery-the-washington-post/>

- Autoimmune conditions include disorders such as polymyalgia rheumatica, rheumatoid arthritis, psoriasis, thyroid disease, lupus and inflammatory bowel disease. Pharmacist, radio show host and syndicated columnist **Joe Graedon** explains how a recent study published in the

BMJ demonstrated that a combination of **fish oil** (marine omega 3 fatty acid supplementation) and **vitamin D** resulted in less incidence of **rheumatoid arthritis**.

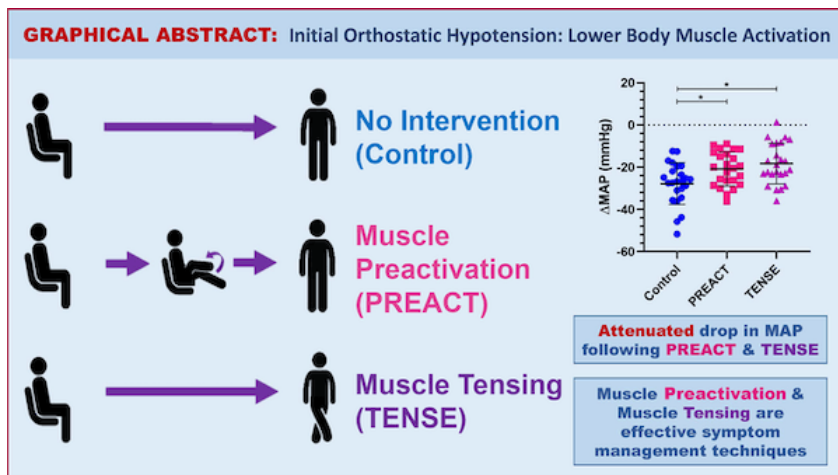
<https://www.peoplespharmacy.com/articles/preventing-autoimmune-diseases-with-vitamin-d-and-fish-oil>

## Physical Techniques for Relief of Dizziness, Vertigo, and Leg Muscle Cramps

- University of Calgary researchers say they've come up with two simple physical techniques to help prevent a common cause of **dizziness** and fainting associated with symptoms of initial **orthostatic hypotension** (IOH), a condition that temporarily leaves people light headed when they stand up. In a small trial of 22 volunteers (all women with IOH), people felt less dizzy when standing after practicing two **easy-to-do physical techniques**.

One method involved pre-activating the muscles behind the reflex from a sitting position, done simply by raising the knees one at a time for up to 30 seconds. The other asked people to stand and then tense up their lower limbs, by crossing their legs and clenching their thighs and butt. The team's findings were published in the journal *Heart Rhythm*.

<https://gizmodo.com/study-how-to-prevent-dizziness-when-standing-1848507098>



Above graphic: the results on the right indicate that volunteers' mean arterial pressure didn't drop as much after trying out either technique.

Graphic: *Heart Rhythm*

- **Vertigo** is a distinct condition from dizziness, and involves a sensation of spinning. During this television episode of "Aging Matters," Cheryl Beversdorf interviews otolaryngologist Patrick Maiberger, M.D. about the symptoms, causes, diagnosis, treatment, and prevention of **vertigo**. The doctor also demonstrates a series of tests on a real patient to determine the cause of his vertigo and demonstrates an "**Epley**" maneuver to relieve the patient's **benign paroxysmal positional vertigo** (BPPV), a common type of vertigo caused by inner ear crystal displacement.

[Aging Matters](https://www.agingmatters.com) web site has an embedded video or you may direct link to 28 minute program:

[https://youtu.be/AaJ9P\\_IaSa4](https://youtu.be/AaJ9P_IaSa4)



Above: Dr. Maiberger performing test on patient with vertigo.

During the program, he says a person may self-administer an "Epley" maneuver, and recommends instructional videos such as those from University of Michigan, House Institute Ear Clinic, or Mayo Clinic. For example of an Epley maneuver demonstration right side, check out this instructional video from University of Michigan:

<https://www.youtube.com/watch?v=BY4UeRmTYmA>

For Epley maneuver left side, see:

<https://www.youtube.com/watch?v=lh72suV2p20>

- The pain of a **charley horse**—which refers to any cramp or involuntary spasm of a muscle, is often experienced in the calf and is triggered by the spasm and balling up of your muscles, says Michael Jaffee, M.D., neurologist at the University of Florida Health. A **simple stretch** can provide relief if you wake up in the middle of the night with a painful charley horse in your calf: "You should forcefully stretch the affected muscle... Point the toes of the affected leg toward your head while keeping the knee extended," says Dr. Jaffee. Check out standing stretches and other tips to avoid muscle cramps.

<https://www.menshealth.com/health/a19546964/leg-cramps-at-night-fix/>

## Covid-19 News

- While Covid-19 cases and deaths have decreased globally, an uptick in cases in the western Pacific region relates to a **new subvariant of Omicron** called BA.2, which is listed as a subvariant of concern by the World Health Organization. BA.2 now accounts for 21.1% of Omicron cases worldwide, according to a WHO update published earlier this week.

<https://www.barrons.com/articles/omicron-covid-19-lineage-51645117161>

- In an unusual six-page announcement, the FDA is discouraging companies from trying to gain approval for "**sanitation tunnels, walkways or chambers**" which spray people and objects with disinfectants or **aerosolized antiseptics** as a way to reduce the spread of Covid-19. The FDA said that it has "significant concerns" about the safety of these tunnels. Such devices have been deployed in China, India, Israel, and other countries, but most of the examples of use are from more than a year ago when we knew less about how the virus that causes Covid-19 was transmitted. It is unclear why the FDA thinks companies may want to bring these to market soon in the U.S.

<https://www.raps.org/news-and-articles/news-articles/2022/2/fda-would-rather-not-have-to-review-sanitation-tun>



- The FDA found that Covid-19 vaccines manufactured by **AstraZeneca** at an **Emergent Biosolutions** facility in Baltimore, Maryland (the same facility also used by Johnson & Johnson that was the source of contaminated vaccines ten months ago), are acceptable for export. However, the FDA states it does not plan on making any more determinations on the fitness for export of additional AstraZeneca lots manufactured at the Emergent facility. AstraZeneca has applied for authorization of its vaccine in the U.S., but the FDA has asked for more data before it will consider the application.

<https://www.reuters.com/business/healthcare-pharmaceuticals/fda-allow-export-astrazeneca-covid-vaccine-lots-made-emergent-plant-2022-02-18/>

- The **Doctors Without Borders**/Médecins Sans Frontières (MSF) organization continues to implore U.S. vaccine company **Moderna** to share its technology and help boost global production of the mRNA vaccine. Although the global mRNA technology transfer hub partner Afrigen recently succeeded in producing **micro-liter laboratory scale batches** of an mRNA vaccine based on the publicly available sequence of the largely publicly funded Moderna vaccine, it says it needs **technical assistance** to shorten the vaccine production timeline. Dr Carrie Teicher, director of programs for MSF-USA said "Time is running out for the US to make good on its claim to be a global leader on COVID-19."

<https://www.doctorswithoutborders.org/what-we-do/news-stories/story/msf-welcomes-who-announcement-six-african-countries-will-receive-tech>

## Covid-19 Statistics

### Cases & Hospital Admissions:

As of February 16, 2022, the 7-day moving average of daily new cases (121,665) decreased 43.0% compared with the previous 7-day moving average (213,625).

The 7-day daily average number of U.S. hospital admissions for February 9–February 15, 2022, was 8,642, a 28.8% decrease from the prior 7-day average (12,142).

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<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

*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.*

**Vaccines:**

As of February 19, 2022, 85.9% of people in the U.S. age 12 and up have received at least one vaccine, while 73.2% of those age 12 and up are fully vaccinated. Approximately 33% of children age 5 to 11 have received one dose of a vaccine (9.3 million children) and 44.7% of people age 12 and older have received a booster dose.

[https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-pop5](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-pop5)

**Global:**

During the week of 7 to 13 February 2022, the global number of new COVID-19 cases decreased by 19% as compared to the number reported during the previous week, while the number of new deaths remained similar to that of the previous week. At the regional level, the **Western Pacific Region** reported an increase of 19% in the number of new weekly cases while all other regions reported decreases.

<https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19--15-february-2022>

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