

News Highlights:

- A teenage boy in Michigan received a double lung transplant after his own lungs were irreparably damaged from a vaping-related injury.

<https://www.sltrib.com/news/health/2019/11/13/facing-certain-death-boy/>

- Just 3 centimeters in diameter and powered by your car's battery, this wireless radar sensor is designed to detect unattended children and animals so that they are not left behind.

[https://uwaterloo.ca/news/news/scientists-develop-sensor-save-children-pets-left-vehicles ...](https://uwaterloo.ca/news/news/scientists-develop-sensor-save-children-pets-left-vehicles...)

- A study of 3 million Canadian prescriptions filled for 89 different medications using brand-name drug discount cards found that overall, the cards were not so cost effective after all.

<https://www.sciencedaily.com/releases/2019/11/1911111100914.htm>

- An expert panel recommended that the FDA approve wider use of Amarin's Vascepa, a prescription-strength fish oil to help prevent heart problems. In a clinical trial, Vascepa cut the combined rate of heart attacks, strokes and other cardiovascular events by 25%. But some critics argued that the use of mineral oil as a placebo in Amarin's trial worsened bad cholesterol levels in patients or affected the absorption of the statin cholesterol drugs they were on, which could have skewed results in favor of Vascepa. Currently the drug is approved for patients with high triglycerides.

[Patient reviews](#) of Vascepa .

<https://www.cnbc.com/2019/11/12/reuters-america-update-1-amarin-surges-as-fish-oil-drug-receives-largely-positive-fda-review.html>

- Kaiser Health News presented alarming statistics on the mental health crisis among youth (age 13-21) in California. Suicides increased by more than 50% in the last ten years and emergency room visits by youth for mental health reasons surged by 42% since 2012.

<https://khn.org/news/more-adolescents-seek-medical-care-for-mental-health-issues/>

- The U.S. Food and Drug Administration approved Novartis' Adakveo (crizanlizumab-tmca), the first approved targeted treatment for sickle cell disease (SCD). The inherited blood disorder, which still has no cure other than blood or bone marrow transplant, is characterized by red blood cells that have a crescent or "sickle" shape. The malformed blood cells limit oxygen delivery to the body's tissues, leading to severe pain and organ damage. Adakveo received rapid approval because of its "Priority Review", "Breakthrough Therapy", and "Orphan Drug" designation. Additional drugs are in the pipeline for treating SCD, which affects 20 million people worldwide, particularly those in Africa or of African descent. All newborns in the U.S. are screened for SCD and also for the sickle cell genetic trait.

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-treat-patients-painful-complication-sickle-cell-disease>

- The FDA strengthened its warning that Biotin supplements (vitamin B7) might interfere with medical lab diagnostic test results. In 2017, the FDA issued a warning that Biotin can interfere with thyroid, troponin, and other tests results, making them falsely high or low, depending on the test. The recent warning emphasizes the risk of **falsely low troponin** lab test results for patients taking higher than normal doses of Biotin. The troponin lab test is used to help diagnose heart attacks. Biotin can be a beneficial dietary supplement and is used in multivitamins, prenatal multivitamins, supplements for hair and skin health, and (in large quantities) for multiple sclerosis. The recommended level of biotin per day is .03 mg; that level does not typically cause interference with lab tests.

<https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety->

[communication](#)

- Beginning in January 2021, hospitals will be required to share price information with consumers— including how big a discount they offer cash-paying patients and rates negotiated with insurers — under a rule finalized by the Trump administration. Not surprisingly, four major hospital organizations said they would challenge the price transparency rule in court. In a companion proposal, now open for public comment, the administration announced a plan to require health insurers to provide up-front information on out-of-pocket costs that patients may expect to pay for healthcare services.

<https://khn.org/news/white-house-unveils-finalized-health-care-price-transparency-rule/>

- Dollar Tree Stores received a warning letter from the FDA for selling over-the-counter medicines sourced from foreign companies with poor, unclean, and/or unsafe manufacturing practices. Dollar Tree responded that they plan to meet with the FDA soon to rectify the problem and also made the point that the drugs mentioned in the warning letter are all products that are applied to the body, not ingested.

<https://www.statnews.com/pharmalot/2019/11/14/fda-dollar-tree-warning-letter/>

Whistle Blower Reveals Project Partnership that Allows Google to Data Mine Tens of Millions of Patient Medical Records

An investigative piece published this week in the *Wall Street Journal* exposed "Project Nightingale," a secret collaboration between Ascension Health (the second-largest healthcare provider in the U.S.) and tech giant Google, involving the transfer of 20 million (soon to be 50 million) complete patient records to Google for various kinds of product development and artificial intelligence-powered applications.

An anonymous whistle blower, who works for Project Nightingale, spoke to the *Wall Street Journal* and also had an essay published on Thursday in *The Guardian* explaining his/her reasons for coming forward. Concerns include the fact that medical information (patient names, dates of birth, lab images, test results, diagnoses, and more) was not de-identified; patients and doctors were not notified of the project; patients could not opt in or out; security concerns about the vulnerability of the vast amounts of medical information being stored on Google's "G-Suite" digital cloud and accessible by too many; lack of an independent watchdog.

Lawmakers and consumer advocates reacted with alarm and demanded an inquiry into the project. Sen. Mark Warner said that the fact that a health care provider could be providing this data to Google, without patient or doctor knowledge or consent, was "deeply unsettling." Senator Amy Klobuchar and Senator Lisa Murkowski called for a federal investigation by the Health and Human Services Office for Civil Rights into whether Health Insurance Portability and Accountability Act (HIPAA) protections have been fully followed.

Some also say that HIPAA regulations, a set of policies originally drafted in 1996 to protect patient privacy, have been influenced more by industry than patient advocates, and that the regulations are also out of date.

Google says it is "HIPAA protected" because it is a business partner of Ascension, but serious questions remain.

The *Brainer Dispatch* reports,

"Under HIPAA, covered entities like hospitals are allowed to share protected health information with 'business associates' to "help the covered entity carry out its health care functions -- not for the business associate's independent use or purposes."

Google reportedly declined to comment on whether it would use patient data for profit or to conduct independent research -- both of which could potentially fall outside the scope of HIPAA protections.

[Sources and more reading on this topic:](#)

- *The Guardian* whistle blower essay published Thursday:

<https://www.theguardian.com/commentisfree/2019/nov/14/im-the-google-whistleblower-the-medical-data-of-millions-of-americans-is-at-risk>

- *CNN*:

<https://www.cnn.com/2019/11/12/tech/google-project-nightingale-federal-inquiry>

- *Wall Street Journal*:

<https://www.wsj.com/articles/google-s-secret-project-nightingale-gathers-personal-health-data-on-millions-of-americans-11573496790> (includes video "Why Big Tech Wants Access to Your Medical Records"; article itself is behind a paywall)

- *Brainer Dispatch*:

<https://www.brainerddispatch.com/news/government-and-politics/4769010-Klobuchar-Murkowski-call-for-HHS-investigation-into-Google-Ascension>

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