



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



October 15, 2021 | Issue 193

Editor's note

This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.



Special Supplement: COVID-19 News

In light of the continuing daily volume of COVID-19 activity and news, we have summarized [COVID-19 news for the week in this special supplement](#).



Healthcare regulatory news

CMS announced that [68% of 2022 MA plans with prescription coverage \(servicing 90% of MA enrollees\) will have an overall rating of four stars or higher](#).

ONC [launched a program](#), building on the U.S. Core Data for Interoperability, to help federal agencies better align and standardize data.

FDA granted [Roche's Alzheimer's drug breakthrough therapy designation](#)... FDA [approved the first smartwatch for blood oxygen and ECG monitoring](#)... FDA authorized [the first e-cigarette](#), stating it could provide benefits to adult cigarette smokers, including reducing exposure to harmful chemicals... FDA [recommended reducing sodium content](#) in commercially processed, packaged, and prepared foods by 12% over the next 2.5 years.



Healthcare law and policy news

Robert Califf [appears to be frontrunner for nomination](#) by President Biden to return to his former role as FDA Commissioner.

Teva asked the [full Federal Circuit court to reconsider a case](#) over generic drug “skinny” labeling.

Walgreens acquired majority stake in [VillageMD \(\\$5.2B\)](#) and [CareCentrix \(\\$330M\)](#)... Molina Healthcare [plans to acquire AgeWell's New York managed long-term-care business \(\\$110M\)](#)... Cigna will [divest its life, accident, and supplemental benefits business in seven countries](#) to Chubb... Pacira BioSciences [will acquire Flexion Therapeutics \(\\$427.5M\)](#)... Best Buy [will acquire Current Health](#)... Headspace and Ginger [finalized their merger](#).

Pfizer will [offer warranties for a lung cancer treatment and refund the cost](#) to any patient and health plan if the medication fails to work within the first three months.

USPSTF [issued draft guidance](#) advising against adults age 60 and older who do not have a history of heart disease or stroke [taking daily low-dose aspirin](#) to prevent heart attacks... CDC [recorded over 96,000 drug overdose deaths](#) in the 12-month period ending in March, up 30% from the preceding year.

Urban Institute estimated [nearly 1 million uninsured children and parents could get insurance coverage](#) if Congress made temporary, enhanced income-based ACA subsidies permanent... RWJF reported the [obesity rate among US children ages 2 to 19 increased from 19.3% in 2019 to 22.4% in 2020](#)... IHI reported [58% of health systems identified health equity as a top priority](#), up from 25% in 2019... A KFF poll found [83% of respondents, including 76% of Republicans, favor allowing](#) the federal government to negotiate prescription drug prices.



Questions or comments, please send to us-hcinsight@kpmg.com.

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COVID-19 News Supplement

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COVID-19 by the Numbers

There have now been [roughly 50.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 720,000... The country is [averaging approximately 91,000 new cases per day](#) over the past week, down 19% over the past two weeks; however deaths per day remained roughly unchanged at 1,900.

405 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 835,000/day over the past week)... Roughly 218 million Americans ([76.8% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; 188 million Americans are fully vaccinated (66.4% of Americans 12 and older); 9.3 million Americans have received a booster dose... Axios reported that [more Americans are getting booster doses per day](#) than are getting first doses.

Executive and Administrative Action

The Biden Administration will [allow non-essential travelers who have been fully vaccinated to enter the US](#) via land or ferry crossings from Canada or Mexico.

The Biden Administration is [moving pandemic tracking data \(HHS Protect\) back over to CDC](#), following the Trump Administration moving the system under management of the HHS Office of the Chief Information Officer.

Healthcare Regulatory News

OMB [began review of an OSHA rule](#) requiring many private sector companies to [mandate employee vaccinations or regular testing](#).

Healthcare Law, Business, and Policy News

Abbott Molecular is [recalling two COVID-19 laboratory test kits](#) due to risk of false-positive results.

Premier estimated that hospitals have [spent more than \\$3 billion on personal protective equipment](#) since the pandemic began.

PointClickCare [announced a contract to provide the CDC](#) with comprehensive, deidentified patient data for residents of long-term and post-acute care facilities, to assess the impact of COVID-19 and other threats on long-term care facility residents.

An [Axios/Ipsos survey found](#) that 42% of Americans trust President Biden a great deal or a fair amount to provide them with accurate information on COVID-19, down 16 percentage points from Inauguration day; meanwhile, 22% report that they've returned to pre-COVID life, down from 28% in June... A National Association of School Nurses-Covid-19 Vaccine Education and Equity Project survey found that

[two-thirds of parents are likely to vaccinate their five to 11 year old](#) children once a vaccine is authorized.

Surveillance, Testing, and Treatment

FDA's Vaccines and Related Biological Products Advisory Committee [voted unanimously in support of authorizing Moderna's COVID-19 vaccine booster](#) to people 65 and older, those 18 to 64 with risk factors for severe COVID-19, and those whose jobs put them at high risk for serious complications... FDA documents prior to the meeting [laid out arguments for authorizing a Moderna booster](#), while also noting that [data so far is unclear](#) on whether a booster is necessary.

The Advisory Committee will [meet today to consider booster shots of Johnson & Johnson's](#) (J&J) COVID-19 vaccines and to discuss mixing and matching doses for different manufacturers... J&J is requesting FDA to authorize its COVID-19 vaccine booster with [varying timing of a second dose](#) from two to six months based on the patient's occupation and health status... FDA data show that protection conferred by J&J's vaccine against moderate to severe COVID-19 decreases over time, from [72% effectiveness two to four weeks post-vaccination to 42% nearly four months after initial shot](#) and that a [booster showed signs of bolstering immunity](#)... NIH data show that people who got the J&J vaccine have a [stronger neutralizing antibody response if they receive an mRNA booster](#) instead of a second J&J shot.

CDC's Advisory Committee on Immunization Practices will [meet October 20 and 21](#) to discuss booster shots of the Moderna and J&J vaccines and meet November 2 and 3 to evaluate vaccines for children under age 12.

Moderna [does not plan to share the formula](#) for its COVID-19 vaccine because company executives believe increasing its own production is a better way to increase global supply... White House Chief Science Officer for COVID-19 response, David Kessler, [strongly criticized Moderna for not providing additional vaccine doses](#) to support global supply and threatened more aggressive government action if the company does not "step up."

CureVac will [stop working on its experimental COVID-19 vaccine](#) and instead focus on a next generation vaccine aimed at variants and boosting protection.

Merck [filed for FDA emergency use authorization](#) for its oral COVID-19 antiviral molnupiravir... FDA's Antimicrobial Drugs Advisory Committee will [meet November 30 to discuss possible emergency use authorization](#) for the drug... Merck plans to [double production capacity next year](#) for the antiviral pill and make cheaper versions through licensing deals with eight generic manufacturers.

AstraZeneca reported that its [injectable antibody cocktail reduced the risk](#) of severe COVID-19 or death by 50% in non-hospitalized patients who have had symptoms for seven days or less... European Medicines Agency [began review of the injectable](#) antibody therapy.

The US government will [manage distribution of GlaxoSmithKline-Vir Biotechnology's monoclonal antibody](#).

The World Health Organization [announced a proposed list of 26 experts](#) for its new Scientific Advisory Group for the Origins of Novel Pathogens to explore the [origins of high-threat pathogens, including COVID-19](#).