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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare</u> <u>Regulatory Insight</u> 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 <u>subscribe to our mailing list</u> here.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply</u> <u>here to me</u>, **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 Administrator Chiquita Brooks-LaSure said CMS <u>will prioritize</u> <u>expanding coverage and health equity</u>... CMMI Director, Liz Fowler, suggested <u>greater use of mandatory</u> alternative payment models... CMS is <u>reevaluating Georgia's approved 1332 waiver to leave HealthCare.gov</u>.

OMB is <u>reviewing an ACA exchange proposed rule</u> rolling back Trump Administration policies.

FDA approved the <u>first KRAS-blocking lung cancer drug</u>... FDA <u>alerted</u> <u>providers to stop using</u> a Medtronic heart implant... FDA <u>recommended</u> <u>improving data exchange</u> between drug tracing systems.

FTC reported on the impacts of "rebate walls" on drug price competition.

ONC <u>will invest \$80M in training/certification programs</u> for institutions serving underrepresented populations.





Healthcare law and policy news

President Biden's FY22 budget <u>proposed</u> increasing <u>HHS spending by 23%</u>.

HHS <u>filed a motion to dismiss a PhRMA lawsuit</u> to block Florida's plan to import prescription drugs from Canada.

Supreme Court <u>rejected Johnson & Johnson's request to review</u> an appeals court decision requiring a \$2.1B payment over links between its talcum powder and ovarian cancer.

Oklahoma's Supreme Court <u>ruled that the governor's plan</u> to privatize much of the state's Medicaid program is unconstitutional... Nevada will enact legislation creating an <u>ACA exchange public-option</u> plan.

Walgreens <u>completed sale of its Alliance Healthcare business</u> to AmerisourceBergen... Doximity <u>filed</u> for <u>a \$100M IPO</u>... Quorum Health <u>sold its consulting division</u> to Grant Avenue Capital... Abiomed <u>acquired preCARDIA</u>... MorphoSys will <u>acquire Constellation Pharmaceuticals</u> (<u>\$1.7B</u>)... Babylon will <u>go public via a SPAC merger</u> (\$4.2B)... Sentara Healthcare and Cone Health <u>ended merger plans</u>.

An NIH <u>phase 1 trial will evaluate the safety</u> of a universal influenza vaccine.





Questions or comments, please send to <u>ushcinsight@kpmg.com</u>.

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COVID-19 by the Numbers

There are now <u>over 33.3 million confirmed COVID-19 cases</u> in the US, with a <u>death toll of over 600,000</u>... The US averaged <u>roughly 16,500 new COVID-19 cases/day over the past week</u>, down 30% from the week before and the lowest since last March; cases declined in 43 states, while staying steady in all others.

298 million COVID-19 <u>vaccine doses have been administered</u> in the US (1M/day over the past week)... 169 million Americans (60.3% of Americans 12 and older and 86% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 136.6 million Americans are fully vaccinated (48.8% of Americans 12 and older)... CDC <u>data show that counties with the highest social vulnerability</u> had a vaccination rate of 49%, compared to 59.3% in the least vulnerable countries... More than <u>2 billion</u> <u>COVID-19 doses have been administered</u> across the world.

Executive and Administrative Action

President Biden <u>declared June a "National Month of Action"</u> to try to meet his goal of vaccinating 70% of the US adult population by July 4; efforts include extended hours at vaccination sites, free ride-sharing to sites, childcare coverage to allow parents to get vaccinated, and competition among cities.

The Biden Administration <u>announced plans for distribution of the first 25 million COVID-19 vaccines</u> that it will donate to low- and middle-income countries, including 19 million to COVAX for countries in South and Central America, Asia, and Africa and 6 million to allies and regional priorities, including Mexico, Canada, West Bank and Gaza, Ukraine, Egypt, and Iraq... The Administration is <u>considering donating</u> states' leftover vaccine doses to foreign countries.

As part of President Biden's proposed budget, CMS requested creation of a \$25 million health equity fund to implement Administration Executive Orders related to identifying systemic barriers to agency programs and taking steps to address the pandemic's disproportionate impacts on communities of color.

HHS launched an upwards of \$500 million venture capital partnership to develop and bring to market innovative technologies to support the country's response to future pandemics.

Healthcare Regulatory News

U.S. Equal Employment Opportunity Commission <u>updated guidance</u> to say that employers <u>can mandate</u> <u>employees receive COVID-19 vaccinations</u>, with reasonable accommodation, and can offer incentives to receive vaccines.

Healthcare Law, Business, and Policy News

World Health Organization (WHO) <u>announced simplified names</u> for COVID-19 variants based on the Greek alphabet... WHO Director-General Tedros Adhanom Ghebreyesus recommended that countries <u>develop an international treaty</u> to prepare for and respond to pandemics.

Several US-based personal protective equipment suppliers have <u>scaled back production of medical</u> <u>gowns and masks or decreased workforce</u> as a result of potentially unfair competition from Chinese manufacturers.

An <u>NIH study found a less than 0.001% chance</u> than an individual will transmit COVID-19 through blood donation, concluding that <u>donation screening requirements are sufficient</u> to prevent spread... A study found that <u>contact tracing efforts had a suboptimal impact</u> on COVID-19 transmission because 2 of 3 cases were not reached for interview or named no contacts when interviewed.

A KFF survey found that <u>just 4% of unvaccinated US adults want a COVID-19 vaccine</u> as soon as possible; 32% of unvaccinated individuals said a full FDA approval would make them more likely to get vaccinated.

Surveillance, Testing, and Treatment

Moderna applied for <u>full FDA approval of its COVID-19 vaccine</u> in people 18 and older... Thermo Fisher Scientific <u>will help manufacture and package Moderna's COVID-19 vaccine</u> beginning in Q3... Moderna will begin <u>producing a revamped version</u> of its vaccine in the Netherlands in partnership with Lonza.

Israeli health officials found a <u>probable link between Pfizer-BioNTech's COVID-19 vaccine and dozens of</u> cases of heart inflammation in young men following a second dose of the vaccine.

AstraZeneca is <u>investigating whether 60 million doses of its COVID-19 vaccine</u> set to be donated to other countries may have been cross-contaminated with Johnson & Johnson's vaccine... AstraZeneca is negotiating with the US government <u>to move production of its vaccine</u> to a factory owned by Catalent... Serum Institute of India will <u>increase production of AstraZeneca's COVID-19 vaccine</u> from about 65 million to 90 million per month.

NIH began a <u>phase 1/2 clinical trial testing whether mixing and matching COVID-19 vaccines</u> can strengthen immunity and combat variants.

WHO, International Monetary Fund, World Bank Group and the World Trade Organization jointly called for a \$50 billion plan to provide vaccines for the developing world... World leaders pledged \$2.4B to support the Gavi COVAX Advance Market Commitment (AMC), aimed at delivering 1.8B COVID-19 vaccine doses to lower-income countries in 2021 and early 2022.

WHO <u>listed China's Sinovac COVID-19 vaccine for emergency use</u>, meaning it can be distributed by COVAX.

NIH Director Francis Collins wrote in a blog post that two new studies confirm that COVID-19 <u>mRNA</u> vaccines "appear to be completely safe for pregnant women."

FDA <u>updated Regeneron's COVID-19 monoclonal antibody</u> emergency use authorization to permit use at half the dose as originally authorized and to be given subcutaneously when intravenous infusion is not possible.