



## Health Policy Briefing

January 17, 2022

### Supreme Court Rules on Vaccine Mandates

Last week, the Supreme Court blocked the enforcement of the administration’s vaccine-or-testing mandate for large employers, while allowing the Centers for Medicare and Medicaid Services (CMS) to implement a rule requiring vaccination among health care workers at federally funded facilities for the 25 states subject to the preliminary injunction. Many Republicans on Capitol Hill were quick to praise the Supreme Court’s decision, including Senate Minority Whip John Thune (R-S.D.) and Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Richard Burr (R-N.C.), who highlighted the pressure placed by the vaccine mandate on an already strained supply chain and labor market. These remarks were echoed by House Energy and Commerce Committee Ranking Member Cathy McMorris Rodgers (R-Wash.), who also stated that GOP Energy and Commerce panel members still plan to lead a Congressional Review Act (CRA) resolution to nullify the health care worker mandate. The resolution was introduced by Rep. Jeff Duncan (R-S.C.) on December 9.

Concerning the health care mandate, Texas is the only state in the country that does not have to comply with the rule. In light of that, the Biden administration has filed a notice to appeal a preliminary injunction granted by the U.S. District Court for the Northern District of Texas. Through its ruling, the Supreme Court lifted injunctions in two separate cases that had blocked the mandate from the Centers for Medicare and Medicaid Services (CMS) in 24 states, determining that Congress has authorized the agency to protect the health and safety of Medicare and Medicaid recipients. Facilities in the 24 states impacted have until March 15 to implement the vaccine requirement for their employees, while facilities in the 25 states not involved in the litigation have until February 28 to ensure employees are fully vaccinated.

Please see [here](#) for a resource document related to the mandates that Hart Health Strategies will continue to update as new information becomes available.

### Inside

Senate to Consider Voting Legislation this Week.....	2
HELP Advances FDA Commissioner Nomination.....	2
WH Under Pressure from Democrats to Step Up COVID Response.....	2
Lawmakers Praise Aduhelm NCD.....	3
Amidst Unprecedented Shortage, Lawmakers Urge Change to Blood Donation Guidelines.....	3
McConnell to Run for Reelection.....	3
Democrat to Fill Late-Hastings Seat.....	3
Katko, Hollingsworth to Retire.....	3
GOP Requests Stakeholder Input on Medical Innovation.....	3
Additional COVID-19 Cases in the House of Representatives.....	4
Regulators Miss Deadline for MDUFA Submission.....	4
CDC Encourages Broader Use of N95s.....	4
Upcoming Congressional Hearings and Markups.....	4
Recently Introduced Health Legislation.....	4

## Senate to Consider Voting Legislation this Week

Majority Leader Chuck Schumer (D-N.Y.) announced last week that the Senate would postpone its scheduled recess to vote on voting rights legislation in the coming days. If the measure is blocked by Republicans, as expected, the chamber will vote on changing the Senate's rules. Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.), however, remain opposed to the elimination of the 60-vote threshold to enable passage of this legislation with a simple majority. President Joe Biden called on the Senate to change its rules to allow a simple majority to pass voting rights legislation during a trip to civil rights landmarks in Atlanta last week.

## HELP Advances FDA Commissioner Nomination

The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced the nomination of Robert Califf to serve as commissioner of the Food and Drug Administration (FDA) in a 13-8 vote. Sens. Bernie Sanders (I-Vt.) and Maggie Hassan (D-N.H.) were the only Democratic members to vote against Califf. Ranking Member Richard Burr (R-N.C.) and Sens. Susan Collins (Maine), Lisa Murkowski (Alaska), and Mitt Romney (Utah) were the only GOP members to back the nominee. Sen. Rand Paul (R-Ky.) was not present for the vote.

Sen. Edward Markey (D-Mass.) has added himself to the list of Democratic senators – which also includes Sens. Richard Blumenthal (D-Conn.), Joe Manchin (D-W.Va.), Bernie Sanders (I-Vt.), and Maggie Hassan (D-N.H.) – who plan to vote against Califf's confirmation. Markey cited concerns about the nominee's ability to address the current substance misuse epidemic and effectively regulate opioid products. Among those currently serving in the Senate are 69 lawmakers who previously voted to confirm Califf to head the FDA during the Obama administration in 2016. His first appointment was approved in an 89-4 vote.

## WH Under Pressure from Democrats to Step Up COVID Response

A group of more than 40 Democrats have sent a [letter](#) to President Joe Biden calling on him to use the power of the executive branch to manufacture enough COVID-19 tests for each American to take one every week. The letter was led by Sen. Bernie Sanders (I-Vt.) and Reps. Adam Schiff (D-Calif.) and Ro Khanna (D-Calif.). A separate group of Senate Democrats penned a [letter](#) to the President about the administration's current state of preparedness and response to the COVID-19 pandemic and the omicron variant. The letter was led by Sen. Jacky Rosen (D-Nev.) and signed by Sens. Joe Manchin (D-W.Va.), Kyrsten Sinema (D-Ariz.), Jon Ossoff (D-Ga.), and Mark Kelly (D-Ariz.). "We ask that you address the steps you have taken to prepare the country for the increase in cases, why the administration failed to take more significant steps earlier to increase access to at-home tests, and how you plan to mitigate the impact of the current and future variants moving forward," the letter states. The lawmakers also ask the administration if any additional funding is necessary to contain the pandemic. The White House is also under pressure to close the global vaccine gap. Seven Democrats led by Sen. Elizabeth Warren (D-Mass.) and Rep. Jan Schakowsky (D-Ill.) sent a [letter](#) last week encouraging the President to immediately mandate transfer of mRNA vaccine technology and to create publicly owned manufacturing facilities to accelerate global production of COVID-19 vaccines. The Biden administration announced that starting on Wednesday, January 19 each residential address can order 4 home tests on a new website, [www.COVIDTests.gov](http://www.COVIDTests.gov).

## Lawmakers Praise Aduhelm NCD

The Centers for Medicare and Medicaid Services (CMS) would limit Medicare coverage of Biogen's Alzheimer's treatment Aduhelm to patients enrolled in qualifying clinical trials under the agency's proposed National Coverage Determination (NCD). The move was praised by House Energy and Commerce Committee Chair Frank Pallone (D-N.J.) and Oversight and Reform Committee Chair Carolyn Maloney (D-N.Y.), who are investigating the approval of Aduhelm amidst concerns about the treatment's safety, efficacy, and cost. The lawmakers also expressed support for the re-evaluation of Medicare Part B premiums based on the NCD and a recent change in the medication's price. Medicare Part B monthly premiums in 2022 were set to increase, in part due to the originally set annual price of \$56,000 for Aduhelm. Biogen recently announced that it would reduce the price by 50% to \$28,200.

## Amidst Unprecedented Shortage, Lawmakers Urge Change to Blood Donation Guidelines

More than 20 Democratic senators have sent a [letter](#) to administration officials urging the Food and Drug Administration (FDA) to update its blood donation guidelines to allow men who have had sex with men to donate blood without a deferral. The lawmakers highlight the "urgent crisis" facing America's blood supply and ask that the agency reassess the existing three-month deferral period for gay and bisexual men. A similar [letter](#) was penned by House Oversight and Reform Committee Chair Carolyn Maloney (D-N.Y.) and signed by Reps. Alexandria Ocasio-Cortez (D-N.Y.), Jamie Raskin (D-Md.), and Katie Porter (D-Calif.).

## McConnell to Run for Reelection

Senate Minority Leader Mitch McConnell (R-Ky.) announced that he will seek another term as GOP leader in the U.S. Senate at the end of this year. McConnell is currently serving his seventh term in the Senate and will not be up for reelection until 2026. The Senate Republican Conference's term-limit rules for leadership positions do not apply to the top leadership post. No Republican senators have announced that they will challenge McConnell for the position.

## Democrat to Fill Late-Hastings Seat

Sheila Cherfilus-McCormick (D) will fill the Florida district #20 seat of the late Rep. Alcee Hastings (D) having defeated Republican challenger Jason Mariner. This increases the Democratic majority in the House of Representatives to 222-212. Cherfilus-McCormick has most recently worked as the CEO of Trinity Health.

## Katko, Hollingsworth to Retire

Adding to the list of lawmakers announcing that they will not run for re-election this year include Rep. John Katko (R-N.Y.) and Rep. Trey Hollingsworth (R-Ind.). Katko has represented the 24th Congressional District of New York since 2015, and currently serves as the ranking member of the House Homeland Security Committee. Hollingsworth has represented Indiana's 9th District since 2017, and currently serves on the House Financial Services Committee.

## GOP Requests Stakeholder Input on Medical Innovation

The Republican Healthy Future Task Force Subcommittee on Treatments has issued a request for information (RFI) from health care stakeholders regarding medical innovation to inform legislation to speed the development and availability of treatments, devices, and diagnostics and to address increasing patient costs. The Republican Healthy Future Task Force was created by House Minority Leader Kevin McCarthy (R-Calif.) as a part of an effort to craft a patient-focused agenda for the future. Parties interested in responding to the RFI should fill out this [form](#) by March 11, 2022.

## Additional COVID-19 Cases in the House of Representatives

More lawmakers have announced that they have tested positive for breakthrough cases of COVID-19. The latest list includes Rep. John Katko (R-N.Y.), Ben Cline (R-Va.), Nancy Mace (R-S.C.), Jim Cooper (D-Tenn.), Sean Casten (D-Ill.), Young Kim (R-Calif.), and Dutch Ruppersberger (D-Md.).

## Regulators Miss Deadline for MDUFA Submission

The Food and Drug Administration (FDA) and the medical device industry have missed a statutory deadline to submit an agreement on a reauthorization of the Medical Device User Fee Amendments (MDUFA) to Congress. While negotiations between the agency and industry are ongoing, there has not been a formal meeting between the two parties since before Thanksgiving. Disagreements remain about an appropriate funding level, how user fees should be spent, the basic structure for the program, and what the cost of a full-time employee is. Last week, the U.S. Department of Health and Human Services (HHS) sent its user fee agreements for prescription drugs, generic drugs, and biosimilars to Congress. If an agreement on medical devices is not reached, it may be necessary for Congress to make updates to the existing MDUFA framework on its own. The current user fee agreements run through the end of the fiscal year (September 30, 2022).

## CDC Encourages Broader Use of N95s

According to updated guidance posted on Friday, the Centers for Disease Control and Prevention (CDC) is now encouraging more Americans to wear N95 or KN95 masks to help slow the spread of coronavirus. The agency had previously been concerned about ensuring an adequate supply of the masks, which better filter the virus from the air, for health care workers. President Joe Biden has also stated that the administration plans to make more high-quality masks available to Americans for free, with more details on this effort expected to be announced this week.

## Upcoming Congressional Hearings and Markups

House Science, Space, and Technology markup of legislation including H.R. 4521, the **Bioeconomy Research and Development Act of 2021** and H.R. 847, the **Promoting Digital Privacy Technologies Act**; 10:00 a.m.; January 19

House Foreign Affairs Europe, Energy, the Environment and Cyber Subcommittee hearing “Transatlantic Cooperation on Critical Supply Chain Security;” 2:00 p.m.; January 19

House Oversight and Reform Subcommittee on the Coronavirus Crisis hearing “A View from the States: Governors Respond to the Omicron Variant;” 3:00 p.m.; January 20

## Recently Introduced Health Legislation

S.3449 — A bill to require foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to register with the Food and Drug Administration regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported into the United States; Sponsor: Sen. Peters, Gary C. [D-MI]; Committees: Senate - Health, Education, Labor, and Pensions

S.3457 — A bill to codify the temporary scheduling order for fentanyl-related substances by adding fentanyl-related substances to schedule I of the Controlled Substances Act; Sponsor: Sen. Cotton, Tom [R-AR]; Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.

- S.3461 — A bill to provide that the rule submitted by the Department of Labor relating to “COVID-19 Vaccination and Testing; Emergency Temporary Standard” shall have no force or effect, and for other purposes; Sponsor: Sen. Braun, Mike [R-IN]; Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.
- S.3463 — A bill to impose sanctions and other measures in response to the failure of the Government of the People’s Republic of China to allow an investigation into the origins of COVID-19 at suspect laboratories in Wuhan; Sponsor: Sen. Rubio, Marco [R-FL]; Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.
- H.R.6363 — To direct the Comptroller General of the United States to conduct a study on funding to entities utilizing such funding for human genomic sequencing or genetic services; Sponsor: Rep. Bucshon, Larry [R-IN-8]; Committees: House - Energy and Commerce
- S.3473 — A bill to authorize funding for the Research, Demonstration, and Evaluation Center for the Aging Network in order to demonstrate the impact of the aging network on the health and independence of older individuals and to foster innovation in such network, and for other purposes; Sponsor: Sen. King, Angus S., Jr. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3476 — A bill to provide for mental health and substance use disorder services in response to public health emergencies, and for other purposes; Sponsor: Sen. Lujan, Ben Ray [D-NM]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3477 — A bill to improve the program for reporting on device shortages; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3478 — A bill to provide for the designation of biological products as qualified infectious disease products; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3479 — A bill to amend the Public Health Service Act with respect to awards to support community health workers and community health; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions
- H.R.6372 — To ensure that facilities of the Indian Health Service, facilities operated by an Indian tribe, tribal organization, or inter-tribal consortium, and facilities operated by an urban Indian organization receive items from the strategic national stockpile and qualified pandemic or epidemic products directly from the Department of Health and Human Services; Sponsor: Rep. Gallego, Ruben [D-AZ-7]; Committees: House - Energy and Commerce
- S.3483 — A bill to amend title 38, United States Code, to extend increased dependency and indemnity compensation paid to surviving spouses of veterans who die from amyotrophic lateral sclerosis, regardless of how long the veterans had such disease prior to death, and for other purposes; Sponsor: Sen. Coons, Christopher A. [D-DE]; Committees: Senate - Veterans’ Affairs
- S.3486 — A bill to provide, manufacture, and distribute high quality N-95 respirator masks for every individual in the United States during the COVID-19 pandemic using the Defense Production Act and other means; Sponsor: Sen. Sanders, Bernard [I-VT]; Committees: Senate - Homeland Security and Governmental Affairs
- S.3489 — A bill to establish or continue a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic, and for other purposes; Sponsor: Sen. Burr, Richard [R-NC]; Committees: Senate - Health, Education, Labor, and Pensions

- S.3493 — A bill to require guidance on extending expiration dates for certain drugs, and for other purposes; Sponsor: Sen. Cardin, Benjamin L. [D-MD]; Committees: Senate - Health, Education, Labor, and Pensions
- H.R.6374 — To implement the recommendations of the Inspector General of the Department of Defense with respect to mitigation of foreign suppliers in the pharmaceutical supply chain of the Department of Defense; Sponsor: Rep. Houlahan, Chrissy [D-PA-6]; Committees: House - Armed Services
- H.R.6377 — To direct the Secretary of Health and Human Services to purchase and make available for free rapid tests for SARS-CoV-2, and for other purposes; Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Energy and Commerce; Financial Services; Ways and Means
- H.R.6384 — To amend the Employee Retirement Income Security Act of 1974, title XXII of the Public Health Service Act, and the Internal Revenue Code of 1986 to improve certain notifications provided to qualified beneficiaries by group health plans in the case of COBRA qualifying events; Sponsor: Rep. Harder, Josh [D-CA-10]; Committees: House - Education and Labor; Energy and Commerce; Ways and Means
- H.R.6385 — To provide, manufacture, and distribute high quality N-95 respirator masks for every individual in the United States during the COVID-19 pandemic using the Defense Production Act and other means; Sponsor: Rep. Khanna, Ro [D-CA-17]; Committees: House - Transportation and Infrastructure; Energy and Commerce; Financial Services; Budget
- S.3496 — A bill to improve research and development of medical countermeasures for novel pathogens; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3497 — A bill to amend the Public Health Service Act to establish a grant program to award grants to public institutions of higher education located in a covered State, and for other purposes; Sponsor: Sen. Inhofe, James M. [R-OK]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3498 — A bill to support endemic fungal disease research, incentivize fungal vaccine development, discover new antifungal therapies and diagnostics, and for other purposes; Sponsor: Sen. Kelly, Mark [D-AZ]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3500 — A bill to amend title XIX of the Social Security Act and the Public Health Service Act to improve the reporting of abortion data to the Centers for Disease Control and Prevention, and for other purposes; Sponsor: Sen. Ernst, Joni [R-IA]; Committees: Senate - Finance
- S.3505 — A bill to amend the Internal Revenue Code of 1986 to exclude certain Nurse Corps payments from gross income; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Finance
- S.3506 — A bill to strengthen the public health workforce loan repayment program, and for other purposes; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions
- S.3509 — A bill to strengthen the authority of the Food and Drug Administration with respect to foreign drug facility inspections; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions
- H.R.6392 — To amend the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs; Sponsor: Rep. Slotkin, Elissa [D-MI-8]; Committees: House - Ways and Means
- H.R.6395 — To prohibit COVID-19 vaccination mandates, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Oversight and Reform; House Administration; Energy and Commerce

H.R.6397 — To amend the Public Health Service Act to establish a grant program to award grants to public institutions of higher education located in a covered State, and for other purposes; Sponsor: Rep. Cole, Tom [R-OK-4]; Committees: House - Energy and Commerce

H.R.6400 — To amend titles XVIII and XIX of the Social Security Act to provide for enhanced payments to rural health care providers under the Medicare and Medicaid programs, and for other purposes; Sponsor: Rep. Graves, Sam [R-MO-6]; Committees: House - Energy and Commerce; Ways and Means; Budget

H.R.6401 — To amend title X of the Public Health Service Act to require recipients of assistance to inform minors receiving family planning services through such assistance about age of consent law, and for other purposes; Sponsor: Rep. Grothman, Glenn [R-WI-6]; Committees: House - Energy and Commerce

H.R.6406 — To elevate the position of Director of the Indian Health Service within the Department of Health and Human Services to Assistant Secretary for Indian Health, and for other purposes; Sponsor: Rep. Stanton, Greg [D-AZ-9]; Committees: House - Natural Resources; Energy and Commerce