



## Health Policy Briefing

February 7, 2022

### House Passes U.S.-Competitiveness Package

The House of Representatives passed the *America COMPETES Act* (H.R. 4521) last week by a vote of 222-210, largely along party lines. The expansive U.S. competitiveness package aims to strengthen U.S. manufacturing and research. The legislation includes \$45 billion over six years for a new *Supply Chains for Critical Manufacturing Industries Fund*. It authorizes \$10 billion to address climate change and deploy clean energy technologies. It also includes the Stopping Harmful Offers on Platforms by Screening Against Fakes in E-commerce Act (H.R. 5374) to protect consumers against the online sale of counterfeit products. There are significant differences between the House legislation and the Senate-passed *U.S. Innovation and Competition Act* (S. 1260), and it remains unclear if or when conferees to reconcile the two bills will be named. The White House has stated that President Joe Biden is eager to sign the China competition bill into law.

### Manchin Looks to Start from Scratch on BBB

While Democrats had hoped to secure Sen. Joe Manchin’s (D-W.Va.) support of a pared-back Build Back Better package to pass a deal by the end of the month, Manchin has characterized the administration’s economic agenda as “dead” and stated that future negotiations should start from scratch. Manchin has repeatedly cited concerns about deficit spending and the reconciliation package’s potential to worsen soaring inflation. He has, however, signaled that a deal could be reached on lowering prescription drug costs and addressing climate change. Sen. Manchin expressed his wish to shift his colleague’s focus to fiscal year (FY) 2022 appropriations bills and legislation to increase U.S. competitiveness with China.

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## Lujan Expected to Make Full Recovery After Stroke

Carlos Sanchez, chief of staff for Sen. Ben Ray Luján (D-N.M.), announced last week that the senator had recently suffered a stroke. As a part of the Senator's treatment plan, he subsequently underwent decompressive surgery to ease swelling. He is currently recovering in the hospital. Luján is expected to make a full recovery and return to the Capitol in four to six weeks barring any complications. His absence in the evenly divided Senate has already delayed votes on some of President Joe Biden's nominees, including nominations to the Federal Communications Commission (FCC) and the Federal Trade Commission (FTC).

## Path Forward for Califf Nomination Unclear

Dr. Robert Califf's nomination to serve as commissioner of the Food and Drug Administration (FDA) remains in limbo, with Sen. Ben Ray Lujan's (D-N.M.) absence following a stroke contributing greater uncertainty to his confirmation status. As a member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, Lujan voted in favor of Califf's nomination. Five Democrats have announced their opposition to Califf's confirmation, citing concerns about his ties to the private sector and ability to address the opioid crisis, while four HELP Committee Republicans voted in support of Califf—leaving him one vote short for full Senate confirmation in Lujan's absence. Sen. Roy Blunt (R-Mo.), a potential supporter of Califf on the Senate floor, told reporters that he has not made a final decision, questioning whether the White House is standing fully behind their nominee. Sens. Rob Portman (R-Ohio) and Pat Toomey (R-Pa.) – two other potential GOP yes votes – said last week that they also remain undecided. Califf recently agreed to not seek employment or compensation from any pharmaceutical or medical device company for four years following his time in government, as well as to recuse himself from FDA matters involving Duke University, to secure the support of Sen. Elizabeth Warren (D-Mass.).

## Biden Meets with Judiciary Leadership on Supreme Court Pick

President Joe Biden consulted with key members of the Senate last week, including Senate Judiciary Committee Chair Dick Durbin (D-Ill.) and Ranking Member Chuck Grassley (R-Iowa) on considerations around his choice to replace retiring Justice Stephen Breyer on the Supreme Court. The President is expected to announce his nominee by the end of the month and has pledged to nominate a Black woman. He has indicated that he will seek Republican support for his candidate. Durbin has said that he expects Senate confirmation of the nominee to take place approximately 40 days after the nomination is announced. Sen. Ben Ray Lujan (D-N.M.), who is currently recovering from a stroke, is expected to return to the Senate by that point; Majority Leader Chuck Schumer's (D-N.Y.) office has said that Lujan's medical situation is not expected to impact the Supreme Court nomination process. Former Sen. Doug Jones (D-Ala.) has been tapped to guide the eventual nominee through the Senate confirmation process.

## President, Lawmakers at Odds on Placement of ARPA-H

President Joe Biden pressured Congress to fund the Advanced Research Projects Agency for Health (ARPA-H) during his relaunch of the Cancer Moonshot initiative last week. The President also pushed for housing ARPA-H within the National Institutes of Health (NIH). The House Energy and Commerce Committee has scheduled a hearing on ARPA-H for this Tuesday. Two measures have been introduced in the House of Representatives to authorize the agency -- one placing ARPA-H within the NIH and the other placing it more generally within the U.S. Department of Health and Human Services (HHS). Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-Calif.), however, has said that ARPA-H will not be made a part of NIH, stating that Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) have backed away from their previous proposal. It remains unclear whether the Senate would follow Rep. Eshoo's lead and create ARPA-H as a standalone entity.

## President to Release FY23 Budget in Coming Weeks

Acting Office of Management and Budget (OMB) Director Shalanda Young stated last week that the President will release his fiscal year (FY) 2023 budget around the time of his State of the Union address, scheduled for March 1. Congress has yet to reach a deal on how to fund the government for the remainder of the current fiscal year. Lawmakers continue to negotiate another short-term continuing resolution (CR), potentially extending through only March 11, with the current February 18 government funding deadline fast approaching.

The *Washington Post* reported last week that the White House may have to ask Congress for additional aid to support coronavirus testing, therapeutics, and vaccines. While supplemental coronavirus resources have been discussed among lawmakers on Capitol Hill, Senate Majority Leader Chuck Schumer (D-N.Y.) has said that they are still awaiting a formal request from the administration. Senate Minority Leader Mitch McConnell (R-Ky.) has questioned whether more spending is really necessary and wishes to first account for unallocated pandemic relief funds.

## House Democrats Push for Consideration of Drug Pricing Measure

A group of more than 40 Democrats in the House of Representatives is [urging](#) leadership to take up legislation to address drug pricing. The lawmakers express support for proposals to allow Medicare to negotiate prices for certain drugs, prohibit manufacturers from increasing prices beyond the rate of inflation, capping out-of-pocket costs for Part D beneficiaries, and ensuring that insulin costs no more than \$35 per month for individuals with insurance. “President Biden supports this plan. We support this plan. Every Democratic member of the U.S. Senate supports this plan. And most importantly, the American people support this plan. It is time to enact it into law,” the letter led by Rep. Susan Wild (D-Pa.) states.

## Markey, Warren Ask DOJ to Act on Counterfeit Masks

Massachusetts Sens. Ed Markey (D) and Elizabeth Warren (D) are asking the Department of Justice (DOJ) to safeguard consumers against retailers selling counterfeit masks. The Centers for Disease Control and Prevention (CDC) recently recommended that respirator face masks – KN95s and N95s – are more effective at preventing COVID-19 transmission than cloth or surgical masks. “We urge the DOJ to redouble its efforts to ensure that consumers are not vulnerable to fraudulent masks...Americans trying to protect themselves, their families, and their communities should not face potentially life-threatening exploitation by unscrupulous actors,” the lawmakers write.

## New Breakthrough COVID Cases on the Hill

House Majority Leader Steny Hoyer (D-Md.) announced that he has tested positive for COVID-19 and is experiencing mild symptoms. Senator John Hoeven (R-N.D.) and Rep. Brad Schneider (D-Ill.) also announced positive tests. In addition, Reps. Sara Jacobs (D-Calif.) and Colin Allred (D-Texas) announced that they have tested positive. Both recently traveled to Ukraine with a bipartisan congressional delegation. All are fully vaccinated and boosted.

## FDA Panel to Consider Vaccine EUA for Children Under Five

The Food and Drug Administration (FDA) has announced a forthcoming meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the request for emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine for use in children six months through four years of age. There are approximately 23 million children less than 5 years of age in the U.S. The VRBPAC meeting will be held on February 15 and will be live-streamed on the agency’s YouTube channel.

## Upcoming Congressional Hearings and Markups

Senate Finance Committee hearing “Protecting Youth Mental Health: Part I – An Advisory and Call to Action;” 10:00 a.m.; February 8

House Energy and Commerce Subcommittee on Health hearing “ARPA-H: The Next Frontier of Biomedical Research;” 10:30 a.m.; February 8

Senate Finance Committee hearing to consider the nominations of Robert Michael Gordon, of the District of Columbia, to be an Assistant Secretary of Health and Human Services and Rebecca E. Jones Gaston, of Oregon, to be Commissioner on Children, Youth, and Families, Department of Health and Human Services; 10:00 a.m.; February 9

House Veterans’ Affairs Subcommittee on Technology Modernization hearing “IT Infrastructure Modernization: Addressing Ongoing Challenges and the Path Forward;” 10:00 a.m.; February 9

Senate Special Committee on Aging hearing “Improving Care Experiences for People with both Medicare and Medicaid;” 9:30 a.m.; February 10

Senate Health, Education, Labor, and Pensions (HELP) Subcommittee on Employment and Workplace Safety hearing “Recruiting, Revitalizing & Diversifying: Examining the Health Care Workforce Shortage;” 10:00 a.m.; February 10

## Recently Introduced Health Legislation

H.R.6512 — To repeal the authority of the Food and Drug Administration to require that drugs be dispensed only upon prescription, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.6513 — To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic devices, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.6514 — To amend the Internal Revenue Code of 1986 to allow an above-the-line deduction for health insurance premiums; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Ways and Means

H.R.6515 — To repeal the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor; Natural Resources; Judiciary; House Administration; Rules; Appropriations

H.R.6519 — To amend the Federal Food, Drug, and Cosmetic Act regarding the patient medication information required to be included in the labeling of prescription drugs, and for other purposes; Sponsor: Rep. Golden, Jared F. [D-ME-2]; Committees: House - Energy and Commerce

H.R.6520 — To require the Secretary of Health and Human Services to establish an automated supply-chain tracking application that provides near real-time insight into the amount of critical medical and health supplies available in the Strategic National Stockpile; Sponsor: Rep. Gottheimer, Josh [D-NJ-5]; Committees: House - Energy and Commerce

H.R.6523 — To authorize the Secretary of Health and Human Services to award grants to a local educational agency or private elementary or secondary school, partnered with a public or nonprofit private health care entity, to develop and implement a comprehensive program to promote student access to defibrillation in elementary schools and secondary schools; Sponsor: Rep. Lawson, Al, Jr. [D-FL-5]; Committees: House - Energy and Commerce; Education and Labor

H.R.6530 — To amend the Public Health Service Act to sustain senior congregate care operations in the wake of ongoing COVID-19 financial burdens, and for other purposes; Sponsor: Rep. Trahan, Lori [D-MA-3]; Committees: House - Energy and Commerce; Ways and Means

S.3534 — A bill to strengthen and expand activities related to genomic sequencing of pathogens, and for other purposes; Sponsor: Sen. Baldwin, Tammy [D-WI]; Committees: Senate - Health, Education, Labor, and Pensions

S.3541 — A bill to improve health care and services for veterans exposed to toxic substances, and for other purposes; Sponsor: Sen. Tester, Jon [D-MT]; Committees: Senate - Veterans' Affairs

S.3548 — A bill to amend title 38, United States Code, to establish a presumption of service-connection for certain veterans with tinnitus or hearing loss, and for other purposes; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Veterans' Affairs

H.R.6534 — To amend the Public Health Service Act to prohibit transplant centers from discriminating against an individual seeking an organ on the basis of whether the individual is vaccinated against COVID-19, and for other purposes; Sponsor: Rep. Cline, Ben [R-VA-6]; Committees: House - Energy and Commerce

H.R.6540 — To amend title III of the Public Health Service Act to prohibit the Organ Procurement and Transplantation Network from requesting the vaccination status of an individual with respect to COVID-19 for the national list of individuals who need organs, and for other purposes; Sponsor: Rep. DesJarlais, Scott [R-TN-4]; Committees: House - Energy and Commerce

H.R.6545 — To amend the Federal Food, Drug, and Cosmetic Act to expand certain authorities with respect to the recall of controlled substances to apply with respect to all drugs, and for other purposes; Sponsor: Rep. Kim, Andy [D-NJ-3]; Committees: House - Energy and Commerce

H.R.6555 — To direct the Administrator of the Federal Emergency Management Agency to designate breast pumps and certain lactation supplies as eligible for certain financial assistance, and for other purposes; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Transportation and Infrastructure

H.R.6557 — To prohibit an employer from terminating the coverage of an employee under a group health plan while the employee is engaged in a lawful strike, and for other purposes; Sponsor: Rep. Axne, Cynthia [D-IA-3]; Committees: House - Education and Labor

H.R.6558 — To ensure that the right to vote shall not be impaired due to vaccination status; Sponsor: Rep. Bishop, Dan [R-NC-9]; Committees: House - Judiciary; House Administration

H.R.6576 — To amend title XVIII of the Social Security Act to extend the Quality Payment Program-Small Practice, Underserved, and Rural Support program; Sponsor: Rep. Welch, Peter [D-VT-At Large]; Committees: House - Energy and Commerce; Ways and Means

S.3569 — A bill to extend the program to provide liability protections for volunteer practitioners at certain health centers; Sponsor: Sen. Thune, John [R-SD]; Committees: Senate - Health, Education, Labor, and Pensions

S.3576 — A bill to allow sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3581 — A bill to direct the Secretary of Health and Human Services to submit to Congress a report on COVID-19 natural immunity, and for other purposes; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education,

## Labor, and Pensions

H.Res.905 — Recognizing the rise of cardiovascular disease as the world's leading cause of preventable death and disability and as the global public health crisis of our generation and supporting the recognition of February 2022, as “American Heart Month”; Sponsor: Rep. Smith, Christopher H. [R-NJ-4]; Committees: House - Energy and Commerce; Foreign Affairs

H.R.6584 — To direct the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes; Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Committees: House - Energy and Commerce

H.R.6593 — To amend the Omnibus Crime Control and Safe Streets Act of 1968 to provide for a pilot program under the Comprehensive Opioid Abuse Grant Program for local law enforcement agencies located in rural areas to purchase naloxone to prevent and reduce opioid overdose deaths, and for other purposes; Sponsor: Rep. Newhouse, Dan [R-WA-4]; Committees: House – Judiciary

H.R.6596 — To amend title 38, United States Code, to clarify that caregivers for veterans with serious illnesses are eligible for assistance and support services provided by the Secretary of Veterans Affairs, and for other purposes; Sponsor: Rep. Ruiz, Raul [D-CA-36]; Committees: House - Veterans' Affairs