



## Health Policy Briefing

October 18, 2021

### President Signs Short-Term Increase to Debt Limit

The House of Representatives voted last week to raise the debt ceiling until December 3. The debt limit bill was previously passed by the Senate and signed into law by President Joe Biden on Thursday. It would increase the nation's borrowing ability by \$480 billion. In absence of the legislation, the government would have breached its borrowing limit and defaulted on its debt obligations around October 18. While the bill prevents an immediate crisis, it sets the stage for another partisan fight over raising the debt limit to coincide with the current deadline to fund the federal government for fiscal year (FY) 2022.

### Biden Expected to Nominate FDA Commissioner in Coming Weeks

Former Commissioner of the Food and Drug Administration (FDA) Robert Califf, MD has emerged as a leading candidate to be nominated to run the agency. President Biden must nominate someone by mid-November for Janet Woodcock to remain in the role of acting Commissioner beyond that time. Califf is a cardiologist and a senior advisor at the Duke Clinical Research Institute. He served as FDA Commissioner during the last year of President Obama's term (February 2016-January 2017). At that time, he was confirmed by the Senate 89-4. More than sixty of the senators who voted for his confirmation serve in the Senate today.

### Reconciliation Negotiations Ongoing

Democrats continue to negotiate what will be included in their multitrillion-dollar social spending package that is expected to be passed via the budget reconciliation process before the end of the year. Lawmakers are working to reduce the total size of the \$3.5 trillion package because of opposition to the topline spending figure by Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.). Manchin and Sinema, however, have yet to make a formal counter proposal on

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either the size of the package or what they want removed from the bill.

Democrats are expected to coalesce around a plan totaling approximately \$2 trillion. House Speaker Nancy Pelosi (D-Calif.) indicated last week that the bill's current drug pricing provisions are likely to be scaled back. Rep. Scott Peters (D-Calif.), one of the holdouts against the party's signature Medicare drug pricing negotiation proposal, has confirmed that talks remain at an impasse. Peters supports an alternative proposal that would not impose an excise tax on drug manufacturers that do not comply with Medicare price negotiations and would only subject drugs whose patents have expired to the negotiation process.

The proposed Medicare expansion plan is also being considered for removal. With a cost of \$350 billion, the addition of hearing, dental, and vision care to the Medicare benefit may be cut to trim the bill to a size acceptable to Senate holdouts. Manchin has expressed opposition to Medicare expansion unless the bill also addresses the program's long-term solvency. Senate Budget Committee Chair Bernie Sanders (I-Vt.), however, has characterized the inclusion of Medicare expansion as non-negotiable, a sentiment echoed by the House Congressional Progressive Caucus.

Both the Senate and the House return from recess this week, working toward an unofficial end of the month deadline to reach an agreement on the reconciliation package. The current surface transportation funding extension expires on October 31 – when lawmakers hope to pass the \$550 billion bipartisan infrastructure framework (BIF). Progressives, however, are standing by their demand that the BIF and reconciliation bills move forward in tandem.

### DeGette, Upton Prepare to Introduce Cures 2.0 This Week

Representatives Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) are expected to officially introduce their Cures 2.0 legislation this week. They aim to pass the bill, a follow up to their 2016 landmark *21st Century Cures Act*, before the end of the year. The bill will include provisions to increase telehealth flexibility, speed the development of cutting-edge treatments, improve clinical trial diversity, increase pandemic preparedness, and authorize the Advanced Research Projects Agency for Health (ARPA-H).

### More than Half of Congress Urges House Leaders to Act on Impending Medicare Cuts

Nearly 200 national and state organizations supported a bipartisan effort in Congress led by Representatives Ami Bera, MD (D-CA) and Larry Bucshon, MD (R-IN) to write House Speaker Nancy Pelosi and Minority Leader Kevin McCarthy urging action before the end of the year to mitigate Medicare provider cuts. 247 bipartisan Members of Congress co-signed the [letter](#) – more than half of the U.S. House of Representatives. The proposed 2022 Medicare Physician Fee Schedule (MPFS) would eliminate a one-time increase of 3.75% provided in 2021 in response to the COVID-19 public health emergency (PHE). The moratorium on the 2% Medicare sequester is also set to expire at the end of the year. Passage of the *American Rescue Plan* and pay-as-you-go requirements may necessitate additional payment cuts of up to 4% next year.

### Lawmakers Push to Expand Global Access to Vaccine Technology

A bicameral group of 12 Democrats is [urging](#) the Biden administration to expand global COVID-19 vaccine access and manufacturing capabilities by sharing Moderna's vaccine technology. The lawmakers argue that the company's contract with the U.S. "may give the federal government legal authority to access and share the ingredient list and manufacturing instructions for Moderna's COVID-19 vaccine." The letter was signed by Senators Elizabeth Warren (D-Mass.), Jeff Merkley (D-Ore.), Tammy Baldwin (D-Wis.), Brian Schatz (D-Hawaii), Tina Smith (D-Minn.), and Sherrod Brown (D-Ohio) and Representatives Pramila Jayapal (D-Wash.), Jan Schakowsky (D-Ill.), Lloyd Doggett (D-Texas), Mark Pocan (D-Wis.), Maxine Waters (D-Calif.), and Raja Krishnamoorthi (D-Ill.).

## Warren, Grassley Look to Speed Hearing Aid Rulemaking

Sens. Elizabeth Warren (D-Mass.) and Chuck Grassley (R-Iowa) have sent a [letter](#) urging the Food and Drug Administration (FDA) to advance regulations related to over-the-counter (OTC) hearing aids. Warren and Grassley authored the ***Over-the-Counter Hearing Aid Act*** passed in 2017 to remove outdated regulations preventing hearing aids from being made available over the counter. The proposed rule to implement the law cleared Office of Management and Budget (OMB) review earlier this month. The letter states that such regulations are necessary to increase access to less expensive hearing devices. The lawmakers ask the agency to issue its proposed rule by November 6, in keeping with President Joe Biden's [Executive Order on Promoting Competition in the American Economy](#).

## Budget Chair Yarmuth Announces Retirement

House Budget Committee Chair John Yarmuth (D-Ky.) has announced that he will not be seeking reelection. Yarmuth was first elected to the House of Representatives in 2006. He stated that he plans to spend his remaining time in office building upon the ***American Rescue Plan***. Morgan McGarvey, Kentucky's State Senate Democratic leader, has announced that he will run for Yarmuth's seat representing the state's 3rd congressional district.

## FDA Panel Approves J&J, Moderna Boosters

The Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to recommend authorizing a booster dose of the Johnson & Johnson COVID-19 vaccine last week. The Advisory Committee unanimously supported the authorization of a second J&J dose as soon as two months after the primary dose for individuals aged 18 and older. The recommendation will be considered by the FDA, which is expected to make a formal decision about a J&J booster in the coming days. The panel also voted to recommend a booster of the Moderna vaccine for individuals 65 and older along with younger individuals at high risk because of a medical condition or their job – the same population currently eligible for a Pfizer-BioNTech booster.

## COVID-19 Antiviral Up for EUA

The Food and Drug Administration (FDA) has announced a forthcoming meeting of its Antimicrobial Drugs Advisory Committee (AMDAC) to discuss an emergency use authorization (EUA) request from Merck and Ridgeback for their investigational antiviral drug molnupiravir for the oral treatment of COVID-19. The panel will meet on November 30 to discuss the available data supporting the use of molnupiravir to treat mild-to-moderate COVID-19 in adults who have tested positive for coronavirus and who are at high risk for progression to severe COVID-19, including hospitalization or death. The committee will hear presentations from the company regarding the data for the antiviral drug, and the FDA will present its perspective regarding the sponsor's data. The meeting will be livestreamed on the FDA's YouTube page and webcast from the FDA's website.

## PHE Declaration Extended

As a result of the continued COVID-19 pandemic, the U.S. Department of Health and Human Services (HHS) has renewed the public health emergency (PHE) declaration [effective October 18](#). The renewal lasts for 90 days and may be extended again by the HHS Secretary. Previously, President Biden has told state officials that he plans to extend the PHE through 2021 and provide a 60-day notice to states when he plans not to renew the PHE. The nationwide PHE was first declared on January 27, 2020.

## Upcoming Congressional Hearings and Markups

Senate Finance Committee hearing “Health Insurance Coverage in America: Current and Future Role of Federal Programs;” 10:00 a.m.; October 20

House Small Business Subcommittee on Oversight, Investigations, and Regulations hearing “Global Supply Chains and Small Business Trade Challenges;” 10:00 a.m.; October 20

House Energy and Commerce Subcommittee on Health legislative hearing “Enhancing Public Health: Legislation to Protect Children and Families;” 10:30 a.m.; October 20

Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy hearing “Protecting Companies and Communities from Private Equity Abuse;” 2:00 p.m.; October 20

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies hearing “Update on VA’s Electronic Health Record Modernization Implementation;” witness: VA Deputy Secretary; 10:00 a.m.; October 21

Senate Judiciary Committee hearing “Oversight of the Department of Homeland Security;” witness: DHS Secretary; 10:00 a.m.; October 21

## Recently Introduced Health Legislation

H.R.5549 — To amend the Indian Health Care Improvement Act to authorize advance appropriations for the Indian Health Service by providing 2-fiscal-year budget authority, and for other purposes. Sponsor: Rep. Young, Don [R-AK-At Large]; Committees: House - Natural Resources; Energy and Commerce; Budget

H.R.5548 — To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to establish a patient outreach system relating to mental health care, and for other purposes. Sponsor: Rep. Wittman, Robert J. [R-VA-1]; Committees: House - Veterans’ Affairs

H.R.5546 — To amend the Public Health Service Act to provide for a Reducing Youth Use of E-Cigarettes Initiative. Sponsor: Rep. Wasserman Schultz, Debbie [D-FL-23]; Committees: House - Energy and Commerce

H.R.5542 — To direct the Secretary of Health and Human Services to establish a grant program to facilitate the distribution of funding for travel related expenses paid by individuals impacted by restrictions to the provision of abortion services, and for other purposes. Sponsor: Rep. Sherman, Brad [D-CA-30]; Committees: House - Energy and Commerce; Judiciary

H.R.5541 — To amend the Internal Revenue Code of 1986 to extend the exemption for telehealth services from certain high deductible health plan rules, and for other purposes. Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Committees: House - Ways and Means

H.R.5540 — To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to cosmetic safety, with an emphasis on communities of color and professional salon workers, and for other purposes. Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce; Education and Labor

H.R.5539 — To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the supply chain transparency needed for companies to make safe cosmetics, and for other purposes. Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.5538 — To amend title VI of the Federal Food, Drug, and Cosmetic Act to provide for greater transparency with respect to fragrance and flavor ingredients in cosmetics, and for other purposes. Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.5537 — To amend the Federal Food, Drug, and Cosmetic Act to ban certain substances in cosmetic products, and for other purposes. Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.5536 — To amend title XVIII of the Social Security Act to revise certain payment rules for outpatient physical therapy and outpatient occupational therapy furnished in rural areas and medically underserved areas, and for other purposes. Sponsor: Rep. Rush, Bobby L. [D-IL-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5530 — To authorize appropriations for the substance abuse youth initiative, and for other purposes. Sponsor: Rep. Neguse, Joe [D-CO-2]; Committees: House - Education and Labor

H.R.5527 — To prohibit the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health from conducting or supporting research on animals in certain foreign countries, and for other purposes. Sponsor: Rep. McClain, Lisa C. [R-MI-10]; Committees: House - Energy and Commerce

H.R.5526 — To amend the Richard B. Russell School Lunch Act to increase access to mental health resources, and for other purposes. Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Education and Labor

H.R.5520 — To amend the Public Health Service Act to increase due process and transparency at the National Library of Medicine in listing and delisting journals in MEDLINE (or any other current or successor databases or indices), and for other purposes. Sponsor: Rep. Jacobs, Chris [R-NY-27]; Committees: House - Energy and Commerce

H.R.5515 — To direct the Secretary of Health and Human Services to ensure that certain biomedical research is conducted in a manner that considers national security risks, and for other purposes. Sponsor: Rep. Dunn, Neal P. [R-FL-2]; Committees: House - Energy and Commerce

H.R.5514 — To amend title XVIII of the Social Security Act to improve extended care services by providing Medicare beneficiaries with an option for cost effective home-based extended care under the Medicare program, and for other purposes. Sponsor: Rep. Cuellar, Henry [D-TX-28]; Committees: House - Ways and Means; Energy and Commerce

H.R.5510 — To ensure that patients receive accurate health care information by prohibiting misleading and deceptive advertising or representation in the provision of health care services, to require the identification of the license of health care professionals, and for other purposes. Sponsor: Rep. Bucshon, Larry [R-IN-8]; Committees: House - Energy and Commerce

H.R.5509 — To amend title 38, United States Code, the Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020, and the Student Veteran Coronavirus Response Act of 2020 to make certain improvements to the educational assistance programs of the Department of Veterans Affairs, and for other purposes. Sponsor: Rep. Bost, Mike [R-IL-12]; Committees: House - Veterans' Affairs

H.R.5506 — To establish a Rural Telehealth Access Task Force to determine how to address barriers to the adoption of telehealth technology and access to broadband internet access service in rural areas, and for other purposes. Sponsor: Rep. Pence, Greg [R-IN-6]; Committees: House - Energy and Commerce; Agriculture

H.Res.718 — Expressing support for the designation of October 17, 2021, as “National Vitiligo Awareness Day”; Sponsor: Rep. Johnson, Henry C. “Hank,” Jr. [D-GA-4]; Committees: House - Energy and Commerce

H.Res.719 — Thanking and promoting the professions of perinatal nurses by encouraging participation in “National Perinatal Nurses Week”; Sponsor: Rep. Roybal-Allard, Lucille [D-CA-40]; Committees: House - Energy and Commerce

H.R.5551 — To amend title III of the Public Health Service Act to reauthorize the National Center on Birth Defects and Developmental Disabilities, and for other purposes; Sponsor: Rep. Carter, Earl L. “Buddy” [R-GA-1]; Committees: House - Energy and Commerce

H.R.5552 — To amend title III of the Public Health Service Act to reauthorize certain programs with respect to lead poisoning, and for other purposes; Sponsor: Rep. Walberg, Tim [R-MI-7]; Committees: House - Energy and Commerce

H.R.5553 — To prohibit the Secretary of Veterans Affairs from providing or paying for surgical treatment related to gender transition; Sponsor: Rep. Bergman, Jack [R-MI-1]; Committees: House - Veterans’ Affairs

H.R.5555 — To establish a manufacturing cluster program, and for other purposes; Sponsor: Rep. Delgado, Antonio [D-NY-19]; Committees: House - Energy and Commerce; Science, Space, and Technology; Armed Services

H.R.5558 — To amend the Public Health Service Act to reauthorize preventive health measures with respect to prostate cancer, and for other purposes; Sponsor: Rep. Dunn, Neal P. [R-FL-2]; Committees: House - Energy and Commerce

H.R.5561 — To reauthorize a program for early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children, and for other purposes; Sponsor: Rep. Guthrie, Brett [R-KY-2]; Committees: House - Energy and Commerce

H.R.5562 — To amend title 38, United States Code, to expand eligibility for hospital care, medical services, and nursing home care from the Department of Veterans Affairs to include veterans of World War II; Sponsor: Rep. Harder, Josh [D-CA-10]; Committees: House - Veterans’ Affairs

H.R.5563 — To amend the Internal Revenue Code of 1986 to allow individuals only enrolled in Medicare Part A to contribute to health savings accounts; Sponsor: Rep. Latta, Robert E. [R-OH-5]; Committees: House - Ways and Means

H.R.5566 — To support fungal disease research, incentivize fungal vaccine development, discover new antifungal therapies and diagnostics, and for other purposes; Sponsor: Rep. McCarthy, Kevin [R-CA-23]; Committees: House - Energy and Commerce

H.R.5575 — To amend title 38, United States Code, to increase the rate of pay for certain nurses and other medical positions of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Veterans’ Affairs

H.R.5576 — To amend titles XIX and XXI of the Social Security Act to give States the option to extend the Medicaid drug rebate program to the Children’s Health Insurance Program, and for other purposes; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Energy and Commerce