



## Health Policy Briefing

February 21, 2022

### Government Funding Extended through March 11

The Senate cleared a three-week stop gap spending bill (H.R. 6617) on a 65-27 vote last week, extending government funding through March 11 and giving lawmakers additional time to complete work on a full year government funding package. The continuing resolution (CR) had been previously passed by the House of Representatives and was signed by President Joe Biden on Friday, averting a government shutdown otherwise set to begin February 19. The latest CR extends government funding at FY 2021 levels with very few exceptions. It also extends the temporary designation of fentanyl as a Schedule I controlled substance through March 11. Appropriators have reached an agreement on the framework for an approximately \$1.5 trillion full-year omnibus spending bill to fund the federal government for the remainder of the fiscal year. Federal agencies have been operating on temporary CRs since the fiscal year began on October 1, 2021. The appropriations subcommittees charged with drafting the 12 annual appropriations bills have each been given tentative spending limits to work within. Lawmakers are still negotiating whether to attach supplemental spending measures to the omnibus legislation. White House officials have begun urging appropriators to include \$30 billion in new spending to combat the COVID-19 pandemic and procure treatments, pediatric vaccines, and variant-specific vaccines. Sen. John Kennedy (R-La.) is also pushing to include disaster relief for Louisiana, Kentucky, New York, and California in the main government funding package. Senate Appropriations Chairman Patrick Leahy (D-Vt.), however, has expressed reservations about attaching any supplementing spending measures to the omnibus bill. Both chambers stand in recess for the Presidents' Day holiday until the week of February 28.

### Dr. Robert Califf Confirmed as FDA Commissioner

The Senate confirmed President Joe Biden's nominee to lead the Food and Drug Administration (FDA) last week by a vote of 50-46. Republican Sens. Roy Blunt (Mo.), Richard Burr (N.C.), Susan Collins (Maine), Lisa Murkowski (Alaska), Mitt Romney (Utah), and Pat Toomey (Pa.) voted in favor of Dr. Robert Califf, a cardiologist and medical researcher, while Sens. Bernie Sanders (I-Vt.) and Democratic Sens.

### Inside

Senate Passes Several Health Measures and Previews Agenda for Coming Weeks.....	2
Warren, King, Doggett Urge WH to Use March-in-Right on Pfizer's Xtandi.....	2
New COVID Protocols for SOTU as GOP Pushes to Reopen Capitol Complex.....	2
GOP Rep. Hagedorn Dies at 59.....	3
NY Rep. Riceto Retire.....	3
Sen. Lujan Returns to DC.....	3
Sen. Wicker, Surgeon General Murthy Test Positive for COVID-19.....	3
FTC Deadlock on PBM Probe.....	3
AMA Releases New Data on Burden of Prior Authorization.....	3
Recently Introduced Health Legislation.....	4

Richard Blumenthal (Conn.), Maggie Hassan (N.H.), Ed Markey (Mass.), and Joe Manchin (W.Va.) voted in opposition. Califf received far less support than when he was first confirmed as FDA Commissioner during the Obama administration by an 89-4 vote. Throughout his most recent confirmation process Califf faced criticisms regarding his ties to industry, ability to respond to the opioid crisis, and the regulation of abortion drugs. Califf gained the support of several lawmakers by agreeing to an enhanced ethics pledge and to not work for industry for four years after leaving the FDA.

Dr. Califf was officially sworn in on Thursday afternoon. The FDA has been without a confirmed leader since President Biden took office, with acting commissioner Janet Woodcock serving at the helm of the agency. Woodcock will remain at the FDA as principal deputy commissioner. “The FDA is one of our nation’s most critical public health agencies and having a commissioner with Dr. Califf’s experience and expertise will ensure we are well positioned to combat COVID-19, the opioid crisis, and many other public health challenges,” U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra said in his statement welcoming Dr. Califf back to the FDA and thanking Dr. Woodcock for her leadership. Califf has committed to improving the agency’s accelerated approval pathway, which has been scrutinized in recent months following the approval of Biogen’s Aduhelm, and to launching a comprehensive review of opioid painkillers. The agency is also working to issue new tobacco and e-cigarette regulations.

### Senate Passes Several Health Measures and Previews Agenda for Coming Weeks

The Senate confirmed Christi A. Grimm as inspector general of the U.S. Department of Health and Human Services (HHS) last week. The chamber also passed the **Dr. Lorna Breen Health Care Provider Protection Act** (H.R. 1667) and the **John Lewis NIMHD Research Endowment Revitalization Act of 2021** (H.R. 189). Both bills will be sent to the President’s desk for his signature. Senate Majority Leader Chuck Schumer (D-N.Y.) has previewed his priorities for the Senate in the coming weeks, taking procedural steps to set up a vote on the **Women’s Health Protection Act of 2021** (H.R. 3755) when the chamber returns the week of February 28. The House-passed legislation would codify Roe v. Wade and is expected to be blocked by Republicans. Other agenda items highlighted by Schumer as priorities include legislation from Sen. Raphael Warnock (D-Ga.) to address the cost of insulin, modeled after the Build Back Better provision to restrict what insured patients pay for insulin to \$35 a month, as well as addressing the differences between the House and Senate passed China competition legislation.

### Warren, King, Doggett Urge WH to Use March-in-Rights on Pfizer’s Xtandi

Sen. Elizabeth Warren (D-Mass.), Sen. Angus King (I-Maine), and Rep. Lloyd Doggett (D-Texas) have sent a [letter](#) to U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra urging him to use existing executive authorities to lower the price of Pfizer’s prostate cancer drug Xtandi. The march-in-rights established by the **Bayh-Dole Act** would allow the federal government to license a company’s patents to outside manufacturers if the government helped fund the product’s research and development. “Exercising the government’s march-in rights for Xtandi will dramatically lower the price of this life-saving drug for millions of Americans,” the lawmakers write. The U.S. government has never before exercised march-in-rights for a manufacturer’s drug patents.

### New COVID Protocols for SOTU as GOP Pushes to Reopen Capitol Complex

All members of Congress will be permitted to attend President Joe Biden’s State of the Union address on March 1, according to a new memo from the Sergeant at Arms. No guests will be allowed to attend. Those in attendance must adhere to COVID-19 health guidelines, including the use of masks, or risk being removed from the event and fined. According to Sens. Chuck Schumer (D-N.Y.) and Dick Durbin (D-Ill.), the President plans to discuss inflation and the economy during his speech.

Sen. Amy Klobuchar (D-Minn.) blocked a resolution introduced by more than half of Senate Republicans to fully reopen the Capitol complex and return to pre-COVID-19 visitor policies. The Capitol has been largely closed to the public since March 2020, with no timeline for reopening. The congressional sergeants-at-arms, in consultation with the Capitol’s attending physician, are responsible for any decisions on changes to the current restrictions.

## GOP Rep. Hagedorn Dies at 59

Rep. Jim Hagedorn (R-Minn.) died at the age of 59 on Thursday. The congressman had been diagnosed with kidney cancer in 2019 and tested positive for COVID-19 last month. He is the son of former Minnesota congressman Tom Hagedorn. Hagedorn was first elected to the House of Representatives in 2018 and served on the Agriculture and Small Business committees. A special election will be held in Minnesota's First Congressional District on August 9 to fill Hagedorn's seat on Capitol Hill.

## NY Rep. Rice to Retire

Rep. Kathleen Rice (D-N.Y.) has announced that she will not be seeking reelection this November. She is the 30th Democrat in the House of Representatives to announce their retirement from the House this election cycle. Rice is a moderate Democrat and former Republican who switched parties in 2005. She was first elected to Congress in 2015, and currently serves on the Energy and Commerce and Homeland Security Committees.

## Sen. Lujan Returns to DC

Sen. Ben Ray Lujan (D-N.M.) has returned to Washington, D.C. where he will complete his recovery after suffering from a stroke in late January. He tweeted that he is "back at work and will return to the Senate floor soon." Lujan is expected to be present to vote by the time the Senate takes up President Joe Biden's nominee to replace retiring Supreme Court Justice Stephen Breyer.

## Sen. Wicker, Surgeon General Murthy Test Positive for COVID-19

Sen. Roger Wicker (R-Miss.) has tested positive for COVID-19. This is the second time he has tested positive for the virus, despite being fully vaccinated. Wicker says that he is "in good health" and will work from home for the next several days. U.S. Surgeon General Vivek Murthy also announced that he, his wife, and his five-year-old son have tested positive for COVID-19.

## FTC Deadlocks on PBM Probe

The Federal Trade Commission (FTC) deadlocked along party lines last week about whether to launch a study of U.S. pharmacy benefit managers (PBMs). Republican commissioners voted against the proposal because it would not, as drafted, consider concerns with the impact of PBMs on out-of-pocket costs for consumers. The study could have been used to inform future efforts to open investigations into certain PBMs.

## AMA Releases New Data on Burden of Prior Authorization

The American Medical Association (AMA) released [new data](#) last week on how prior authorization delays timely access to care, adversely impacts patient outcomes, and places unnecessary burdens on health care providers. According to the AMA's survey, more than half of physicians report that prior authorization interfered with their patient's access to care. Four-in-five physicians report that their patients abandoned treatment due to prior authorization struggles with their health plan, and more than one-third report that prior authorization led to serious adverse events including hospitalization, disability, and even death. Rep. Suzan DelBene (D-Wash.) and Sen. Roger Marshall (R-Kansas), sponsors of the *Improving Seniors' Timely Access to Care Act* (S. 3018/H.R.3173), each issued a statement asserting that this new data further underscores the shortcomings of current prior authorization practices and urging their colleagues to support the legislation to streamline the prior authorization process.

H.R.6713 — To amend the Controlled Substances Act with respect to the scheduling of fentanyl-related substances, and for other purposes. Sponsor: Rep. Johnson, Mike [R-LA-4]; Committees: House - Energy and Commerce; Judiciary

H.R.6711 — To prohibition Federal spending on funding research in China, and for other purposes. Sponsor: Rep. Herrell, Yvette [R-NM-2]; Committees: House - Science, Space, and Technology

H.R.6710 — To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices, and for other purposes. Sponsor: Rep. Herrell, Yvette [R-NM-2]; Committees: House - Energy and Commerce

H.R.6709 — To amend the Elementary and Secondary Education Act of 1965 to include certain mental health professionals as specialized instructional support personnel. Sponsor: Rep. Harder, Josh [D-CA-10]; Committees: House - Education and Labor

H.R.6704 — To prohibit the use of Federal funds to purchase, or support the purchase of, drug paraphernalia. Sponsor: Rep. Bishop, Dan [R-NC-9]; Committees: House - Energy and Commerce

S.J.Res.39 — A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Department of Health and Human Services relating to “Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs; Sponsor: Sen. Thune, John [R-SD]; Committees: Senate - Health, Education, Labor, and Pensions

S.3641 — A bill to extend protections to part-time workers in the areas of family and medical leave and pension plans, and to ensure equitable treatment in the workplace; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3645 — A bill to prohibit the use of Federal funds for local substance use disorder services for the purchase of sterile needles or syringes for the injection of illegal drugs, or to procure, supply, or distribute pipes, cylindrical objects, or other paraphernalia that can be used to smoke, inhale, or ingest narcotics; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.3648 — A bill to amend the DNA Sexual Assault Justice Act of 2004 to increase access to Sexual Assault Nurse Examiners, and for other purposes; Sponsor: Sen. Cornyn, John [R-TX]; Committees: Senate – Judiciary

H.R.6733 — To amend the Internal Revenue Code of 1986 to prohibit the Internal Revenue Service from requiring taxpayers to provide biometric information; Sponsor: Rep. Huizenga, Bill [R-MI-2]; Committees: House - Ways and Means

H.R.6735 — To amend the DNA Sexual Assault Justice Act of 2004 to increase access to Sexual Assault Nurse Examiners, and for other purposes; Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House – Judiciary

H.R.6744 — To prohibit the use of Federal funds for local substance use disorder services for the purchase of sterile needles or syringes for the injection of illegal drugs, or to procure, supply, or distribute pipes, cylindrical objects, or other paraphernalia that can be used to smoke, inhale, or ingest narcotics; Sponsor: Rep. McKinley, David B. [R-WV-1]; Committees: House - Energy and Commerce

S.3656 — A bill to amend title XVIII of the Social Security Act to provide hereditary cancer genetic testing for individuals with a history of a hereditary cancer gene mutation in a blood relative or a personal or ancestral history suspicious for hereditary cancer, and to provide coverage of certain cancer screenings or preventive surgeries that would reduce the risk for individuals with a germline (inherited) mutation associated with a high risk of developing a preventable cancer; Sponsor: Sen. Murkowski, Lisa [R-AK]; Committees: Senate – Finance

S.3658 — A bill to amend the Higher Education Act of 1965 to provide for interest-free deferment on student loans for borrowers serving in a medical or dental internship or residency program; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.3660 — A bill to amend the Internal Revenue Code of 1986 to make diapers an allowable expense for purposes of health flexible spending arrangements and health savings accounts; Sponsor: Sen. Ernst, Joni [R-IA]; Committees: Senate – Finance

S.3670 — A bill to clarify that agencies of the Department of Health and Human Services do not have the authority to regulate the practice of medicine; Sponsor: Sen. Johnson, Ron [R-WI]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.518 — A resolution expressing the sense of the Senate that in order to effectively address the high prevalence of individuals suffering from mental health conditions and substance use disorders, the United States needs to make historic financial investments into mental health and substance use disorder care and finally acknowledge such care as a priority in health care equal to physical health, and for other purposes; Sponsor: Sen. Warnock, Raphael G. [D-GA]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.523 — A resolution designating February 28, 2022, as “Rare Disease Day”; Sponsor: Sen. Brown, Sherrod [D-OH]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.3675 — A bill to amend title XVIII of the Social Security Act to establish a system to notify individuals approaching Medicare eligibility; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate – Finance

S.3686 — A bill to amend the Public Health Service Act to provide education and training on eating disorders for health care providers and communities, and for other purposes; Sponsor: Sen. Klobuchar, Amy [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3688 — A bill to authorize the Secretary of Health and Human Services, acting through the Director of the Center for Mental Health Services of the Substance Abuse and Mental Health Services Administration, to award grants, contracts, or cooperative agreements to facilitate the funding of community-based mental health and substance use disorder services and peer support programs, and for other purposes; Sponsor: Sen. Warnock, Raphael G. [D-GA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3696 — A bill to establish the position of Interagency Coordinator for Behavioral Health to coordinate the programs and activities of the Federal Government relating to mental health, and for other purposes; Sponsor: Sen. Warnock, Raphael G. [D-GA]; Committees: Senate - Homeland Security and Governmental Affairs

S.3700 — A bill to provide for appropriate cost-sharing for insulin products covered under Medicare part D and private health plans; Sponsor: Sen. Warnock, Raphael G. [D-GA]; Committees: Senate – Finance

S.3704 — A bill to amend the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants, contracts, or cooperative agreements to schools and school-based health centers to increase the number of behavioral health care providers in such schools and health centers, and for other purposes; Sponsor: Sen. Warnock, Raphael G. [D-GA]; Committees: Senate - Finance