



## Health Policy Briefing

November 15, 2021

### Robert Califf Nominated as FDA Commissioner

President Joe Biden has selected Robert Califf to serve as commissioner of the Food and Drug Administration (FDA). Califf is a cardiologist and a senior advisor at the Duke Clinical Research Institute. He most recently worked for the life sciences research group Verily and Google Health. He previously served as FDA Commissioner during the last year of President Obama’s term (February 2016-January 2017). Janet Woodcock, former Director of the Center for Drug Evaluation and Research (CDER), has been serving as acting commissioner since January, and the White House faced a legal deadline of mid-November to nominate a permanent commissioner or choose another acting commissioner.

Sens. Joe Manchin (D-W.Va.) and Richard Blumenthal (D-Conn.) have expressed opposition to Califf’s nomination given his ties to the pharmaceutical industry. The lawmakers were joined by Sen. Ed Markey (D-Mass.) in voting against his confirmation in 2016. Markey has said that he is still reviewing Califf’s record from his earlier time spent at the head of the FDA. Califf was previously confirmed by the Senate in an 89-4 vote. More than sixty of the senators who voted for his confirmation continue to serve in the Senate today. The President has urged the Senate to quickly confirm Califf given the ongoing COVID-19 pandemic.

### House Awaits CBO Score of Reconciliation Package

Congress returns from recess this week hoping to make progress on the \$1.75 Trillion Build Back Better reconciliation package along with other must-pass items before the end of the year. The House of Representatives delayed a vote on the tax and social spending legislation in response to several requests from moderate Democrats to wait for the official Congressional Budget Office (CBO) cost estimate of the bill. CBO has said that it will provide a score for the legislation “as soon as practicable” and has been its score piecemeal through the past week. The reconciliation package is still expected to be modified when it reaches the Senate, both to pass the Senate’s rules for the reconciliation process and to gain the necessary support of every Senate Democrat. Sen. Joe Manchin (D-W.Va.) has already expressed reservations about some of the key provisions of the bill and has called for slowing the pace of negotiations. Democratic leadership have expressed their hope of passing the

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reconciliation bill before Thanksgiving. Congress also faces several deadlines the week following its Thanksgiving recess, including the expiration of the current continuing resolution (CR) funding the federal government on December 3 and the date by which Congress must formally raise the nation's debt limit or risk a default. Negotiations on an omnibus appropriations package have stalled, given a disagreement between Democrats and Republicans over topline defense and non-defense spending figures.

### Doc Caucus Expresses Concern Re: Surprise Billing Regulation

The GOP Doctors Caucus is [urging](#) the Biden administration to revise its proposed regulation to implement the *No Surprises Act*. The lawmakers argue that the interim final rule (IFR) released on September 30 detailing the parameters of the independent dispute resolution (IDR) process “does not reflect legislation that could have passed Congress or the law as written.” The letter states that major revisions are needed to align with the statute and congressional intent, specifying that “the final law explicitly required an independent entity to consider a broad range of criteria and weigh all relevant factors equally when deciding appropriate payments for out-of-network services.”

### Investigation Launched Into Unregulated, Synthetic Nicotine

House Economic and Consumer Policy Subcommittee Chair Raja Krishnamoorthi has sent [letters](#) to Next Generation Labs LLC and Puff Bar regarding their manufacturing and sale of synthetic nicotine. Krishnamoorthi asserts that some companies that have been banned by the Food and Drug Administration (FDA) from selling their products plan to switch to the production of synthetic nicotine to avoid regulation. He asks the firms to supply documents and answer a series of questions by November 22.

## Upcoming Congressional Hearings and Markups

House Oversight and Reform Committee hearing “Cracking Down on Ransomware: Strategies for Disrupting Criminal Hackers and Building Resilience Against Cyber Threats;” 10:00 a.m.; November 16

House Oversight and Reform Subcommittee on National Security hearing “Invisible Wounds: Preventing Suicide in Our Nation's Military and Veteran Communities;” 10:00 a.m.; November 17

House Homeland Security Subcommittee on Cybersecurity, Infrastructure Protection & Innovation and Intelligence & Counterterrorism hearing “A Whole-of-Government Approach to Combatting Ransomware: Examining DHS's Role;” 10:00 a.m.; November 17

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing “U.S. Role in Global COVID-19 Vaccine Equity;” 10:30 a.m.; November 17

House Transportation and Infrastructure Committee hearing “Industry and Labor Perspectives: A Further Look at North American Supply Chain Challenges;” 10:30 a.m.; November 17

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis hearing “Combating Coronavirus Cons and the Monetization of Misinformation;” 2:00 p.m.; November 17

House Veterans' Affairs Subcommittee on Oversight and Investigations hearing “Modernizing VA's Medical Supply Chain: Progress Made?” 10:00 a.m.; November 18

Senate Judiciary Committee markup of the Better Cybercrime Metrics Act (S. 2629); 9:00 a.m.; November 18

H.R. 5892 – A bill to prohibit the denial of any Federal benefit, to which an individual is entitled by reason of service as a member of the Armed Forces, solely on the basis of the refusal of such individual to receive a vaccination against COVID-19; Sponsor: Rep. Babin, Brian [R-TX-36]; Committee: House – Oversight and Reform

H.R. 5894 – A bill to prohibit the use of Federal funds for gender transition in minors; Sponsor: Rep. Boebert, Lauren [R-CO-03]; Committee: House – Education and Labor

H.R. 5898 – A bill to protect covered entities that take measures to comply with the guidelines of the Centers for Disease Control and Prevention to prevent or mitigate the spread of the virus that causes COVID-19, and for other purposes; Sponsor: Rep. Frankel, Lois [D-FL-21]; Committee: House – Energy and Commerce

H.R. 5908 – A bill to provide that Executive Orders 14042 and 14043 shall have no force or effect; Sponsor: Rep. Wenstrup, Brad [R-OH-02]; Committee: House – Oversight and Reform

H.J. Res. 62 – A joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the interim final rule of the Occupational Safety and Health Administration relating to “COVID-19 Vaccination and Testing; Emergency Temporary Standard”; Sponsor: Gosar, Paul [R-AZ-04]; Committee: House – Education and Labor

H. Res. 779. A resolution expressing the sense of the House of Representatives that Congress Disapproves of the Occupational Safety and Health Administration’s Vaccine Mandate; Sponsor: Gibbs, Bob [R-OH-07]; Committee: House – Education and Labor

H.Res.784 — Expressing the sense of the House of Representatives that the United States recognizes the mounting personal and financial burden of diet-related disease in the United States and calls on medical schools, graduate medical education programs, and other health professional training programs to provide meaningful physician and health professional education on nutrition and diet; Sponsor: Rep. McGovern, James P. [D-MA-2]; Committees: House - Energy and Commerce; Ways and Means

H.Res.786 — Expressing support for the designation of November 9, 2021, as “National Microtia and Atresia Awareness Day”; Sponsor: Rep. Neguse, Joe [D-CO-2]; Committees: House - Energy and Commerce

H.Con.Res.60 — Expressing the sense of Congress that the United States Government must take steps to end the pandemic now; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Foreign Affairs; Ways and Means; Judiciary; Financial Services

H.R.5932 — To amend titles XVIII and XIX of the Social Security Act to provide for the improvement of patient safety and to reduce the incidence of injury and death from opioid-induced respiratory depression under the Medicare and Medicaid programs; Sponsor: Rep. Kuster, Ann M. [D-NH-2]; Committees: House - Energy and Commerce; Ways and Means

H.R.5934 — To amend the Child Nutrition Act of 1966 to support women, infants, and children impacted by substance use disorder, and for other purposes; Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Education and Labor

H.R.5935 — To prohibit adverse action against a member of the Armed Forces solely on the basis that such member refuses to receive a vaccination against COVID-19 or disclose whether such member has received such a vaccination; Sponsor: Rep. Mast, Brian J. [R-FL-18]; Committees: House - Armed Services

H.R.5937 — To increase language access to mental health services at certain health centers, and for other purposes; Sponsor: Rep. Meng, Grace [D-NY-6]; Committees: House - Energy and Commerce

H.R.5938 — To direct the Secretary of Veterans Affairs to conduct a review on opioid overdose deaths among veterans, and for other purposes; Sponsor: Rep. Murphy, Gregory [R-NC-3]; Committees: House - Veterans' Affairs

H.R.5941 — To amend title 38, United States Code, to provide for priority in the award of State home facility grants to nursing homes and domiciliaries from States that the Secretary determines have a great or significant need for beds and which are located at least 100 miles away from the nearest existing State home facility; Sponsor: Rep. O'Halleran, Tom [D-AZ-1]; Committees: House - Veterans' Affairs

H.R.5942 — To amend title 10, United States Code, to eliminate increases in the enrollment fee requirement for TRICARE Select for certain retired members of the Armed Forces, and for other purposes; Sponsor: Rep. Stauber, Pete [R-MN-8]; Committees: House - Armed Services

H.R.5947 — To amend title 38, United States Code, to assign the highest priority status for hospital care and medical services provided through the Department of Veterans Affairs to veterans who are former prisoners of war; Sponsor: Rep. Walberg, Tim [R-MI-7]; Committees: House - Veterans' Affairs