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Health Policy Briefing

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VP Harris and Others Test Positive for COVID-19

Vice President Kamala Harris has tested positive for COVID-19. While she was not experiencing symptoms, after consulting with her physicians, Harris was prescribed Pfizer Inc.'s Paxlovid COVID-19 therapy. In accordance with the administration's test-to-treat initiative, the White House recently moved to permit all pharmacies to order the COVID-19 therapy pill to increase access to the treatment as the supply of the drug increases. Harris is not considered to have been in close contact with President Joe Biden. She is the highest-ranking administration official to report being infected. Sens. Ron Wyden (D-Ore.) and Chris Murphy (D-Conn.) also reported that they had tested positive for coronavirus last week. These recent cases impacted confirmation votes in the evenly divided Senate where Harris serves as the tie-breaking president. The chamber was expected to vote on Federal Reserve and Federal Trade Commission nominations, but the votes were postponed due to the absence of the COVID positive Democrats. It was also recently reported that Sen. Michael Bennet (D-Colo.), Rep. Maxine Waters (D-Calif.) and White House Communications Director Kate Bedingfield had tested positive for COVID-19. While Bedingfield had a socially distanced meeting with President Biden earlier in the week, she was not considered a close contact to the President as defined by the Centers for Disease Control and Prevention.

Democrats Seek to Tie COVID Relief to Ukraine Aid

Lawmakers continue to negotiate a COVID-19 response package containing an additional $10 billion in funding for testing, treatment, and vaccines. Senate Democrats are pushing to combine the COVID bill with a $33 billion aid package for Ukraine. How leadership will proceed remains unclear, given disagreements over tying Title 42 restrictions to the package. The Biden administration recently announced that it will rescind the policy,

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which allows the White House to restrict immigration based on public health concerns, by May 23. That decision has been challenged in court, with a federal judge in Louisiana issuing a temporary restraining order against the phasing out of Title 42. Only the Senate will be in session this week. The House of Representatives stands in a one-week district work period and is scheduled to return on May 10.

Manchin Seeks to Revive Reconciliation Bill to Address Inflation

After a meeting with Senate Majority Leader Chuck Schumer (D-N.Y.) last week, Sen. Joe Manchin (D-W.Va.) stated that he is open to using the budget reconciliation process to pass legislation to address soaring inflation, and that the bill should also include proposals to lower the cost of prescription drugs. Manchin was the sole Democratic holdout responsible for stalling the $2 trillion ***Build Back Better*** reconciliation package last year. While Schumer characterized his meeting with Manchin as "preliminary and good" and stated that conversations will continue, many are still skeptical that an agreement can be reached on a reconciliation bill. Although Manchin has expressed support for tax changes and deficit reduction measures, Sen. Kyrsten Sinema (D-Ariz.) stands strongly opposed to raising the corporate tax rate. Other Democrats, including Sens. Amy Klobuchar (D-Minn.) and Ron Wyden (D-Ore.), have told reporters in recent weeks that they are nearing an agreement on a domestic policy package that includes climate change measures and provisions to reduce inflation and drug prices, but there is currently no timetable for passage.

Lawmakers Push to Prioritize Medicaid Expansion

Sen. Raphael Warnock (D-Ga.) and Rep. Carolyn Bourdeaux (D-Ga.) spearheaded a letter to congressional leadership last week about the importance of including Medicaid expansion in any future reconciliation package. The lawmakers assert that the Medicaid gap "results in preventable suffering, death, and tragedy, and the costs of care when it's too late are inevitably born by the public…It is bad public health policy, and it is bad fiscal policy." The letter was signed by 29 other lawmakers. Twelve states in the nation have yet to expand their Medicaid programs.

Healthy Future Task Force Releases Set of Treatment Recommendations

The Treatment Subcommittee of the GOP's Healthy Future Task Force has released its key findings and policy solutions to promote new life-saving cures and lower drug costs. The Healthy Future Task Force was created by House Minority Leader Kevin McCarthy (R-Calif.) in June 2021 to examine strategies to modernize the American health care system and lower costs, keep Americans healthy, develop better therapies, and cures, and provide Americans with more health care choices. The Treatment Subcommittee's plan recommends:

- Passage of H.R. 19, the ***Lower Costs, More Cures Act***;
- Building off bipartisan proposals that allow for innovations in paying for curative therapies;
- Offering incentives for health plans to share drug discounts with patients directly at the pharmacy counter;
- Speeding up the Food and Drug Administration approval process to bring more treatments to patients quickly;
- Expanding and speeding up Medicare coverage for breakthrough drugs and devices;
- Giving seniors access to new, innovative blood tests to diagnose cancers earlier;
- Banning the use of quality-adjusted life years from all coverage and payment decisions;
- Making clinical trials more widely available;
- Incentivizing domestic medical manufacturing of therapies and therapeutics to prepare for the next pandemic;
- Promoting sufficient supply of testing and personal protective equipment; and
- Ensuring secure access to critical ingredients for medicine.

Burr Stresses Need for FDA Accountability in UFA Hearing

The Senate Health, Education, Labor, and Pension Committee held its second hearing on the latest reauthorization of the user fee agreements negotiated between the Food and Drug Administration (FDA) and medical industry. During the hearing last week, panel members heard from the heads of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Ranking Member Richard Burr (R-N.C.) stressed the need for the agency to be held accountable for meeting the terms of its commitments in the user fee programs. Burr noted that the FDA missed 12 out of 14 user fee goals in the new drug program related to product development meetings with sponsors, only reviewed 50% of biosimilars applications on time, and was three months late in finalizing a medical device user fee agreement.

In related news, Senate Majority Whip Dick Durbin (D-Ill.) is pushing to include his bipartisan ***Dietary Supplement Listing Act*** (S. 4090) in the must-pass user fee legislation. The bill aims to improve dietary supplement oversight to better identify potentially harmful ingredients and health impacts. The legislation would require manufacturers to list their products with the FDA and report information on ingredients, directions for use, safety warnings, and claims about health and function. Manufacturers and distributors of the 50,000 to 80,000 dietary supplements available in the U.S. are not currently required to register their products and ingredients with the FDA. In its FY 2023 budget request, the agency proposed requiring an annual listing of supplement products and asked Congress to clarify its authority over dietary supplements. The user fee agreements must be reauthorized before the current agreements expire on September 30.

Eshoo Continues Effort to Separate ARPA-H from NIH

House Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-Calif.) stated last week during a subcommittee hearing on the U.S. Department of Health and Human Services (HHS) FY 2023 budget that she will continue working to keep the newly established Advanced Research Projects Agency for Health (ARPA-H) outside the National Institutes of Health (NIH). Under HHS Secretary Xavier Becerra's plan, published in the Federal Register on April 20, ARPA-H would be housed within NIH, but its director would report directly to the HHS secretary. The move came after Congress appropriated $1 billion for the new entity in its FY 2022 omnibus spending package. Authorizing legislation is still pending in both the Senate and House of Representatives. Eshoo stated that she will push to advance her ARPA-H authorizing legislation (H.R. 5585, the ***Advanced Research Project Agency-Health Act***) that would set up ARPA-H as an independent HHS agency. Eshoo has repeatedly voiced concerns that tethering ARPA-H to the NIH bureaucracy will not allow the new agency to nimbly achieve the breakthrough research and development it was established to accomplish.

Hassan, Braun Ask FDA to Update Opioid Labeling Regulations

Sens. Maggie Hassan (D-N.H.) and Mike Braun (R-Ind.) sent a letter to the Food and Drug Administration (FDA) last week urging the agency to update its opioid prescription labeling policies. The lawmakers detail the number of individuals in each of their states who have lost their lives due to opioid overdoses and argue that many who die from an overdose first become addicted through a legal prescription for OxyContin or other FDA-approved drugs. "Despite this harm," the letter states, "the FDA continues to permit doctors to prescribe these drugs to be sold under misleading and inaccurate labels…an urgent priority must be to update the FDA's opioid labeling policies to reflect current public health and safety knowledge."

Warren Urges WH to Use Executive Authority to Lower Rx Drug Prices

Sen. Elizabeth Warren (D-Mass.) sent a letter to U.S. Department of Health and Human Services Secretary Xavier Becerra last week detailing steps the Biden administration can take on its own to lower drug prices. She outlines several executive actions and existing authorities identified by legal and public health experts that can be used without congressional approval "to give sorely needed relief to the millions of Americans paying far too much for their prescription drugs." These include the government patent use power, march-in rights on a patent, and invoking royalty-free licenses.

OR, KY to Launch Basic Health Programs

Oregon and Kentucky have announced plans to use the Affordable Care Act's (ACA) basic health program to establish an affordable health insurance option for people who make too much money to qualify for Medicaid coverage. An estimated 85,000 individuals in Oregon and at least 37,000 in Kentucky will be eligible to enroll in the plans as early as next year. Concerns have been raised about the number of people that will become ineligible for Medicaid or lose their expanded ACA subsidies at the end of this year as the COVID-19 public health emergency (PHE) winds down. Minnesota and New York were the only states to establish a basic health program upon its creation in 2014. A basic health program offers insurance for people who make up to twice the federal poverty level – about $55,000 for a family of four – and do not qualify for Medicaid.

FDA Announces Tentative COVID Vaccine Meeting Schedule

The Food and Drug Administration (FDA) has announced its tentative advisory committee meeting schedule in anticipation of complete submissions of emergency use authorization (EUA) requests in the coming months that have been publicly announced by COVID-19 vaccine manufacturers:

- On June 7, FDA intends to convene the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss an EUA request for a COVID-19 vaccine manufactured by Novavax to prevent COVID-19 in individuals 18 years of age and older.
- On June 8, 21, and 22, the FDA has held dates for the VRBPAC to meet to discuss updates to the Moderna and Pfizer-BioNTech EUAs for their COVID-19 vaccines to include younger populations.
- On June 28, the FDA plans to convene the VRBPAC to discuss whether the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified and if so, which strain(s) should be selected for Fall 2022. This meeting is a follow-up to the April 6 VRBPAC meeting that discussed general considerations for future COVID-19 vaccine booster doses and the strain composition of COVID-19 vaccines to further meet public health needs.

FDA Moves to Ban Menthol Cigarettes, Flavored Cigars

The Food and Drug Administration (FDA) has released two proposed regulations that would ban menthol flavoring in cigarettes and all characterizing flavors in cigars. The FDA had announced plans last year to pursue these policies as a part of its efforts to address health disparities and reduce the death and disease caused by combusted tobacco product use. Smoking products with menthol flavoring are disproportionately used by Black Americans.

GAO Releases Report on CDC Data Modernization Initiative

The Government Accountability Office (GAO) has released a report finding that the Centers for Disease Control and Prevention's (CDC) Data Modernization Initiative is too vague, lacking in deadlines, and without a clear delineation of responsibility for completing the project. The initiative was launched in 2020 as a part of a broader effort to improve the nation's public health information systems and improve the nation's response to public health threats like the coronavirus pandemic. GAO asserts that while the CDC has been given $1.1 billion to proceed with the project, it has yet to fully detail plans for spending the money.

Richmond to Depart WH for DNC Post

Former Congressman Cedric Richmond will leave his post as a top aide to President Joe Biden to join the Democratic National Committee (DNC). Richmond has led the White House Office of Public Engagement since the start of President Biden's time in office. He leaves to support the DNC's work raising campaign funds and promoting the party's message in the lead-up to the midterm elections this fall.

Upcoming Congressional Hearings and Markups

Senate Appropriations Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies hearing to examine proposed budget estimates and justification for fiscal year 2023 for the Department of Health and Human Services; 9:30 a.m.; May 4

Senate Commerce, Science, and Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security hearing "Ensuring Fairness and Transparency in the Market for Prescription Drugs;" 10:00 a.m.; May 5

Recently Introduced Health Legislation

S.Res.595 — A resolution designating the week of April 18 through April 24, 2022, as "National Osteopathic Medicine Week"; Sponsor: Sen. Manchin, Joe, III [D-WV]; Submitted in the Senate, considered, and agreed to without amendment by Unanimous Consent.

S.4088 — A bill to prohibit the Secretary of Health and Human Services from lessening the stringency of, and to prohibit the Secretary of Homeland Security from ceasing or lessening implementation of, the COVID-19 border health provisions through the end of the COVID-19 pandemic, and for other purposes; Sponsor: Sen. Cruz, Ted [R-TX]; Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.

S.4090 — A bill to improve transparency and availability of information regarding dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to list dietary supplements with the Food and Drug Administration; Sponsor: Sen. Durbin, Richard J. [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7573 — To amend titles XI and XVIII of the Social Security Act to extend certain telehealth services covered by Medicare and to evaluate the impact of telehealth services on Medicare beneficiaries, and for other purposes; Sponsor: Rep. Axne, Cynthia [D-IA-3]; Committees: House - Energy and Commerce; Ways and Means; Judiciary

H.R.7577 — To improve State, local, and Tribal public health security; Sponsor: Rep. Gallego, Ruben [D-AZ-7]; Committees: House - Energy and Commerce

H.R.7585 — To improve the health of minority individuals, and for other purposes; Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Committees: House - Energy and Commerce; Agriculture; Oversight and Reform; Ways and Means; Education and Labor; Judiciary; Budget; Veterans' Affairs; Natural Resources; Armed Services; Homeland Security; Financial Services; Transportation and Infrastructure

H.R.7586 — To amend title III of the Public Health Service Act to provide for suspension of entries and imports from designated countries to prevent the spread of communicable diseases and import into the United States of certain controlled substances; Sponsor: Rep. Lesko, Debbie [R-AZ-8]; Committees: House - Energy and Commerce

H.R.7589 — To amend title 38, United States Code, to prohibit the imposition or collection of copayments for certain mental health outpatient care visits of veterans, and for other purposes; Sponsor: Rep. Takano, Mark [D-CA-41]; Committees: House - Veterans' Affairs

H.R.7591 — To amend the Public Health Service Act to include Middle Easterners and North Africans in the statutory definition of a "racial and ethnic minority group", and for other purposes; Sponsor: Rep. Tlaib, Rashida [D-MI-13]; Committees: House - Energy and Commerce

S.4091 — A bill to amend part A of title XI of the Social Security Act to provide grants to States, units of local government, and Indian Tribes to establish, expand, or maintain Drug Overdose Fatality Review Teams; Sponsor: Sen. Whitehouse, Sheldon [D-RI]; Committees: Senate – Finance

S.4100 — A bill to amend title XIX of the Social Security Act to provide coverage under the Medicaid program for services provided by doulas and midwives, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate – Finance

H.R.7608 — To authorize the Secretary of Health and Human Services to award grants to States to develop, improve, or maintain a State registry of advance directives; Sponsor: Rep. Suozzi, Thomas R. [D-NY-3]; Committees: House - Energy and Commerce

S.Res.602 — A resolution expressing support for the designation of April 30, 2022, as "National Adult Hepatitis B Vaccination Awareness Day"; Sponsor: Sen. Hirono, Mazie K. [D-HI]; Committees: Senate - Health, Education, Labor, and Pensions

S.4120 — A bill to maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes; Sponsor: Sen. Reed, Jack [D-RI]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.1069 — Expressing support for the designation of May 7 each year as "Brain Donation Awareness Day"; Sponsor: Rep. Blumenauer, Earl [D-OR-3]; Committees: House - Energy and Commerce

H.Res.1072 — Expressing support for the designation of April 30, 2022, as "National Adult Hepatitis B Vaccination Awareness Day"; Sponsor: Rep. Johnson, Henry C. "Hank," Jr. [D-GA-4]; Committees: House - Energy and Commerce

H.R.7617 — To provide for a national public health education campaign, grant program, and task force for recommended preventive health care services during the COVID-19 pandemic and future pandemics, and for other purposes; Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Committees: House - Energy and Commerce

H.R.7630 — To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes; Sponsor: Rep. McCaul, Michael T. [R-TX-10]; Committees: House - Energy and Commerce

H.R.7634 — To amend title XI of the Social Security Act to prohibit the use of quality-adjusted life years and similar measures in coverage and payment determinations under Federal health care programs; Sponsor: Rep. McMorris Rodgers, Cathy [R-WA-5]; Committees: House - Energy and Commerce; Ways and Means