



Health Policy Briefing

May 23, 2022

E&C Advances FDA User Fee, Mental Health Packages

The House Energy and Commerce Committee advanced six health care bills to the floor last week. A must-pass package, the **Food and Drug Amendments of 2022** ([H.R. 7667](#)), reauthorizing medical product user fee programs at the Food and Drug Administration (FDA) for another five years was approved by a bipartisan 55-0 vote. The panel agreed to an amendment from Rep. G.K. Butterfield (D-N.C.) based on his **Give Kids a Chance Act** ([H.R. 6972](#)), which would give FDA the authority to require that manufacturers investigating a drug combination targeting adult cancer also develop a pediatric study plan to inform labeling for children. The current user fee agreements expire on September 30.

The committee also advanced comprehensive mental health legislation ([H.R. 7666](#)) by voice vote. The **Restoring Hope for Mental Health and Well-Being Act** aims to address the nation’s worsening overdoses crisis by increasing funding for and access to mental health services. It would also renew several mental health programs. During the markup, the panel adopted an amendment to the bill that would add training requirements for prescribers of controlled substances.

The **ARPA-H Act** ([H.R. 5585](#)) was advanced by a vote of 53-3. The bipartisan bill would authorize the new biomedical innovation hub known as the Advanced Research Projects Agency for Health (ARPA-H) as an independent agency within the U.S. Department of Health and Human Services (HHS). The ARPA-H director would be subject to presidential appointment and Senate confirmation. The legislation, which would prohibit ARPA-H’s headquarters from sitting on any part of the existing National Institutes of Health (NIH) campuses, would conflict with steps already taken by HHS Secretary Xavier Becerra to establish ARPA-H as an agency inside NIH. The House bill would provide HHS six months to transfer ARPA-H into an independent operating division. The Senate’s ARPA-H authorizing language, contained in the **PREVENT Pandemics Act** ([S. 3799](#)), would place ARPA-H within the NIH but require the agency to be headquartered outside the national capital region. Lawmakers have already begun pressing the administration to choose their state for the placement of ARPA-H, with Massachusetts’ and Texas’ congressional delegations both reportedly lobbying

Secretary Becerra to headquarter ARPA-H within their states. During the Reagan-Udall Foundation for the FDA annual public meeting held last week, FDA Principal Deputy Commission Janet Woodcock previewed how

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the agency will interact with the newly established ARPA-H. Woodcock stated that the FDA will be “deeply involved” in the work of ARPA-H, but that the new biomedical research agency may intensify the recent debate around the accelerated approval process and the appropriate balance between the certainty of a product’s clinical benefit and the speed of access to patients in FDA’s review of future ARPA-H discoveries.

HELP Releases Draft FDA UFA Package

Leadership of the Senate Health, Education, Labor, and Pensions (HELP) Committee released their bipartisan discussion draft, the [FDA Safety and Landmark Advancements \(FDASLA\) Act](#), to reauthorize the medical product user fee programs at the Food and Drug Administration (FDA) for another five years last week. The package would also expand the agency’s authority over how cosmetics, dietary supplements, and laboratory-developed tests (LDTs) are regulated. It includes provisions from the [Dietary Supplement Listing Act \(S. 4090\)](#) that would require manufacturers and distributors of dietary supplements to register their products with the FDA. It would also require makers of cosmetic products to register with the FDA and would provide the agency with the authority to discontinue products with harmful ingredients. The [VALID Act](#), which would reform the way the FDA regulates diagnostic tests, is also included in the package. In response to the FDA and medical device industry failing to reach an agreement before the statutory deadline during this most recent negotiating period, the draft bill contains new requirements that the negotiating parties provide regular details about user fee discussions and publish meeting minutes within 30 days. Unlike the House version of the reauthorization, the bill does not propose to revise the FDA’s accelerated approval process or place additional requirements for the reporting of medical device shortages. HELP accepted public comments on the legislative draft through May 22. The programs must be reauthorized before the current user fee agreements expire on September 30.

WH Signals Renewal of PHE

The U.S. Department of Health and Human Services (HHS) will renew the COVID-19 public health emergency (PHE) declaration beyond the current expiration of July 16. The White House previously stated that it will provide a 60-day notice before terminating or allowing the PHE declaration to expire. In the absence of a public announcement from the White House last week, the current PHE expires in less than 60 days. Therefore, another three-month extension of the PHE declaration, and the regulatory flexibilities that accompany it, through October are expected. The Biden administration continues to reiterate its calls for Congress to approve additional funding for pandemic response. A \$10 billion coronavirus emergency funding package looks to be stalled until at least mid-June, being lower in priority than the Congressional response to the infant formula shortage and passage of military and humanitarian aid to Ukraine. A deal on the latest COVID-19 bill fell apart last month because of Republican opposition to the administration’s lifting of Title 42 immigration restrictions. Democrats are weighing the option of supplemental border security funding to evade a vote on Title 42 attached to the COVID-19 aid package. The House of Representatives is not scheduled to have any votes between now and June 6. The Biden administration has warned that supplies of key COVID-19 therapies, including the monoclonal antibody bebtelovimad, the antibody treatment Evusheld, and the antiviral Paxlovid are at risk of being exhausted by the fall.

Insulin Bill Pushed to Summer

Sens. Susan Collins (R-Maine) and Jeanne Shaheen (D-N.H.) said they are waiting for a cost estimate from the Congressional Budget Office (CBO) on their legislation to lower the price of insulin and cap patients’ costs for their medication. Sen. Raphael Warnock (D-Ga.), whose bill to cap what people pay for insulin at \$35 per month is being combined with the Collins-Shaheen proposal, had pushed for a May vote on the insulin legislation. The need for a CBO score means Senate consideration of the proposal will likely not take place until later this summer. CBO found that a similar proposal introduced in the House of Representatives ([H.R. 6833](#)) would increase federal spending by more than \$6.5 billion. It remains to be seen whether the bipartisan legislation could garner the 60 votes necessary to pass the Senate.

Lawmakers Reach Agreement on Veteran Burn Pit Bill

Bipartisan leadership of the Senate Veterans Affairs Committee has reached an agreement to consider legislation to support veterans who have been exposed to toxic substances during military deployments. The deal is based on the *Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (PACT) Act* ([H.R. 3967](#)), introduced by House Veterans Affairs Committee Chair Mark Takano (D-Calif.). The bill would increase access to medical care and disability benefits for veterans by establishing presumptions of service connection related to toxic exposure, and by adding 23 burn pit and toxic exposure-related conditions to the VA's list of service presumptions.

New Analysis of Lowering Medicare Eligibility Age

The Congressional Budget Office (CBO) and Joint Committee on Taxation have released a new [analysis](#) examining the budgetary effects of a policy that would lower the age of eligibility for Medicare to 60. The agencies found that expanding Medicare to Americans over age 60 would add 7.3 million people to the program and increase the budget deficit by \$155 billion over five years. Lowering the eligibility age from 65 to 60 would also decrease the number of individuals with employer-sponsored health coverage by 3.2 million and lower the uninsured rate for the newly eligible population from 8% to 4%. The report indicates that 150,000 people would retire early having no need to remain in their job for the purpose of health insurance coverage.

Van Hollen Recovering from Minor Stroke

Sen. Chris Van Hollen (D-Md.) was admitted to George Washington Hospital after suffering a minor stroke. Van Hollen was informed that there would be no long-term effects as a result of the small venous tear. He stated that he was “on the mend and on track for a full recovery,” and that he would be easing back into his schedule per his doctors’ orders.

Becerra COVID Positive

U.S. Department of Health and Human Services Secretary Xavier Becerra tested positive for COVID-19 last week while traveling in Berlin for G7 meetings for health ministers. Becerra is fully vaccinated and boosted and experiencing mild symptoms. He continued to work while in isolation in Berlin. Becerra was not considered a close contact to President Joe Biden.

Upcoming Congressional Hearings and Markups

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing “Fiscal Year 2023 Member Day;” 10:00 a.m.; May 24

House Energy and Commerce Subcommittee on Oversight and Investigations hearing “Formula Safety and Supply: Protecting the Health of America’s Babies;” 11:00 a.m.; May 25

House Appropriations Subcommittee on Defense hearing “Defense Health and Medical Readiness;” 12:00 p.m.; May 25

Senate HELP Committee executive session to consider the nomination of Rita Landgraf to be Assistant Secretary for Aging, Department of Health and Human Services; time TBD; May 25

Senate Indian Affairs Committee nomination hearing to consider Roselyn Tso to be Director of the Indian Health Service, Department of Health and Human Services; 2:30 p.m.; May 25

Senate Finance Committee hearing “Supply Chain Resiliency: Alleviating Backlogs and Strengthening Long-Term Security;” 3:00 p.m.; May 25

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Public Witness Day hearing; 10:00 a.m.; May 26

Senate Environment and Public Works Committee hearing to examine Toxic Substances Control Act amendments implementation; 10:00 a.m.; June 22

Recently Introduced Health Legislation

H.R.7775 — To extend the National Alzheimer’s Project. Sponsor: Rep. Tonko, Paul [D-NY-20]; Committees: House - Energy and Commerce

H.R.7774 — To streamline the employer reporting process and strengthen the eligibility verification process for the premium assistance tax credit and cost-sharing subsidy. Sponsor: Rep. Thompson, Mike [D-CA-5]; Committees: House - Ways and Means; Energy and Commerce

H.R.7773 — To require an annual budget estimate for the initiatives of the National Institutes of Health pursuant to reports and recommendations made under the National Alzheimer’s Project Act. Sponsor: Rep. Smith, Christopher H. [R-NJ-4]; Committees: House - Energy and Commerce

H.R.7770 — To amend the Family and Medical Leave Act of 1993 to permit additional leave for bone marrow or blood stem cell donation, and for other purposes. Sponsor: Rep. Phillips, Dean [D-MN-3]; Committees: House - Education and Labor; Oversight and Reform; House Administration

H.R.7767 — To amend the Employee Retirement Income Security Act of 1974 to provide for the enforcement of mental health and substance abuse disorder parity requirements, and for other purposes. Sponsor: Rep. Courtney, Joe [D-CT-2]; Committees: House - Education and Labor

H.Res.1116 — Expressing support for the annual Childhood Apraxia of Speech Awareness Day on May 14, 2022, coinciding with Better Hearing and Speech Month. Sponsor: Rep. Malliotakis, Nicole [R-NY-11]; Committees: House - Energy and Commerce

S.Res.635 — A resolution designating May 2022 as “ALS Awareness Month”; Sponsor: Sen. Cotton, Tom [R-AR]; Latest Action: Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

H.Res.1118 — 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

H.R.7780 — To support the behavioral needs of students and youth, invest in the school-based behavioral health workforce, and ensure access to mental health and substance use disorder benefits; Sponsor: Rep. DeSaulnier, Mark [D-CA-11]; Committees: House - Education and Labor

H.R.7784 — To amend the SUPPORT for Patients and Communities Act to improve trauma support services and mental health care for children and youth in educational settings, and for other purposes; Sponsor: Rep. Hayes, Jahana [D-CT-5]; Committees: House - Education and Labor

H.R.7786 — To amend the Public Health Service Act to limit certain authority of the Department of Health and Human Services to require individuals to wear a mask, a face covering, or any other accessory during domestic air travel, to require the refund of civil fines imposed for refusal to wear such an accessory, and for other purposes; Sponsor: Rep. Mullin, Markwayne [R-OK-2]; Committees: House - Transportation and Infrastructure; Energy and Commerce; Homeland Security

S.Res.637 — A resolution expressing support for viewing women’s health as a critical issue for the economy and workforce of the United States and for advancing the health and well-being of all people; Sponsor: Sen. Duckworth, Tammy [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.642 — A resolution expressing support for the designation of May 17, 2022, as “DIPG Pediatric Brain Cancer Awareness Day” to raise awareness of, and encourage research on, diffuse intrinsic pontine glioma tumors and pediatric cancers in general; Sponsor: Sen. Rubio, Marco [R-FL]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4234 — A bill to amend title XVIII of the Social Security Act to make improvements to the redistribution of residency slots under the Medicare program after a hospital closes; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate – Finance

S.4235 — A bill to amend the Controlled Substances Act to fix a technical error in the definitions; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate – Judiciary

H.Res.1129 — Expressing support for viewing women’s health as a critical issue for the economy and workforce of the United States and for advancing the health and well-being of all people; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.7798 — To amend title IV of the Public Health Service Act to prohibit sale or transactions relating to human fetal tissue; Sponsor: Rep. Franklin, C. Scott [R-FL-15]; Committees: House - Energy and Commerce

H.R.7803 — To amend title XIX of the Social Security Act to remove the exclusion from medical assistance under the Medicaid program of items and services for patients in an institution for mental diseases, and for other purposes; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Energy and Commerce

S.4244 — A bill to amend the Toxic Substances Control Act to prohibit the manufacture, processing, use, and distribution in commerce of commercial asbestos and mixtures and articles containing commercial asbestos, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Environment and Public Works

S.4256 — A bill to amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods; Sponsor: Sen. Casey, Robert P. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7810 — To amend the Toxic Substances Control Act to prohibit the manufacture, processing, use, and distribution in commerce of commercial asbestos and mixtures and articles containing commercial asbestos, and for other purposes; Sponsor: Rep. Bonamici, Suzanne [D-OR-1]; Committees: House - Energy and Commerce

H.R.7814 — To amend the Public Health Service Act to authorize grants to health care providers to enhance the physical and cyber security of their facilities, personnel, and patients; Sponsor: Rep. Escobar, Veronica [D-TX-16]; Committees: House - Energy and Commerce

H.R.7823 — To amend the Internal Revenue Code of 1986 to make the health coverage tax credit permanent; Sponsor: Rep. Kildee, Daniel T. [D-MI-5]; Committees: House - Ways and Means

H.R.7828 — To amend the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.7831 — To amend the Internal Revenue Code of 1986 to provide a deduction for certain charity care furnished by physicians, and for other purposes; Sponsor: Rep. Webster, Daniel [R-FL-11]; Committees: House - Ways and Means

S.4260 — A bill to amend the Public Health Service Act to increase the number of permanent faculty in palliative care at accredited allopathic and osteopathic medical schools, nursing schools, social work schools, and other programs, including physician assistant education programs, to promote education and research in palliative care and hospice, and to support the development of faculty careers in academic palliative medicine; Sponsor: Sen. Baldwin, Tammy [D-WI]; Committees: Senate - Health, Education, Labor, and Pensions

S.4264 — A bill to amend title XIX of the Social Security Act to require States to develop a strategy to integrate and coordinate Medicaid and Medicare coverage for full-benefit dual eligible individuals; Sponsor: Sen. Scott, Tim [R-SC]; Committees: Senate - Finance

S.4268 — A bill to amend the Public Health Service Act to authorize grants to health care providers to enhance the physical and cyber security of their facilities, personnel, and patients; Sponsor: Sen. Gillibrand, Kirsten E. [D-NY]; Committees: Senate - Health, Education, Labor, and Pensions

S.4269 — A bill to amend the Public Health Service Act to establish a program to award grants to State, local, and Tribal governments to purchase and distribute anti-blood loss supplies for use in a medical emergency, and for other purposes; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.4273 — A bill to amend title XIX of the Social Security Act to provide States with resources to support efforts to integrate or coordinate Medicare and Medicaid benefits for individuals that are eligible for both programs; Sponsor: Sen. Casey, Robert P. [D-PA]; Committees: Senate - Finance

S.4286 — A bill to direct the Attorney General to develop crisis intervention training tools for use by first responders related to interacting with persons who have a traumatic brain injury, another form of acquired brain injury, or post-traumatic stress disorder, and for other purposes; Sponsor: Sen. Ossoff, Jon [D-GA]; Committees: Senate - Judiciary

S.4288 — A bill to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a biological product; Sponsor: Sen. Lujan, Ben Ray [D-NM]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7834 — To amend title XVIII of the Social Security Act to prohibit the Secretary of Health and Human Services from selecting certain activities relating to the development of anti-racism plans as clinical practice improvement activities under the Medicare program; Sponsor: Rep. Palmer, Gary J. [R-AL-6]; Committees: House - Energy and Commerce; Ways and Means

H.R.7845 — To direct the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, to take certain steps to increase clinical trial diversity, and for other purposes; Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Committees: House - Energy and Commerce

H.R.7850 — To amend the Public Health Service Act to establish a program to award grants to State, local, and Tribal governments to purchase and distribute anti-blood loss supplies for use in a medical emergency, and for other purposes; Sponsor: Rep. O'Halleran, Tom [D-AZ-1]; Committees: House - Energy and Commerce

H.R.7857 — To amend title V of the Public Health Service Act to reauthorize the Minority Fellowship Program; Sponsor: Rep. Watson Coleman, Bonnie [D-NJ-12]; Committees: House - Energy and Commerce