



Health Policy Briefing

June 13, 2022

House Passes UFA Legislation

The House of Representatives passed [H.R. 7667](#) to reauthorize medical product user fees at the Food and Drug Administration (FDA) through fiscal year (FY) 2027 last week. The bill was passed under suspension of the rules in a 392-28 vote. The Congressional Budget Office’s estimated budgetary effects of the *Food and Drug Amendments of 2022* was released several days before House passage and can be found [here](#). Among other things, the package includes provisions to revamp the agency’s accelerated approval process and increase clinical trial diversity.

The Senate continues to work on its own version of the reauthorization package. The two proposals differ in several respects, such as the inclusion of clinical trial diversity measures and a pediatric cancer research provision (based on [H.R. 6972](#), the *Give Kids a Chance Act*) in the House bill. Unlike the House version, the Senate’s bill includes language to overhaul the cosmetic, dietary supplement, and laboratory-developed test (LDT) regulatory framework. Leadership have not stated how they will reconcile the differences between the two bills. The Health, Education, Labor, and Pensions Committee is scheduled to markup the Senate’s bipartisan bill on June 14. Sen. Bernie Sanders (I-Vt.) has already told reporters that he plans to offer an amendment to allow for the importation of prescription drugs during the markup. Lawmakers aim to send user fee legislation to the President’s desk before the congressional August recess. The current user fee authorization will expire at the end of the fiscal year on September 30.

House to Consider ARPA-H Next Week

The House of Representatives will consider legislation ([H.R. 5585](#)) to establish the Advanced Research Projects Agency for Health (ARPA-H) the week of June 20, according to Majority Leader Steny Hoyer (D-Md.). The chamber will also consider the package advanced by the House Energy and Commerce Committee to address the opioid abuse and mental health crisis, as well as legislation from the Education and Labor Committee on mental health, addiction, and suicide on college campuses. Finally, the House will vote on the *STRONG Veterans Act* ([H.R. 6411](#)), which aims to combat veteran suicide.

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Senate Reaches Bipartisan Agreement on Gun Violence Framework

Senate negotiators, led by Sens. Chris Murphy (D-Conn.) and John Cornyn (R-Texas), have reached a bipartisan deal on a narrow set of gun safety measures with enough support to overcome a filibuster in the evenly-divided chamber. The package would include funding for mental health resources and school security as well as grants to states to enact red flag laws. It would also expand the nation's background check system to include juvenile records for any prospective gun buyer under the age of 21. The lawmakers must now translate these measures into legislative text. The plan currently has the endorsement of 10 Republicans and 10 Democrats. Majority Leader Chuck Schumer (D-N.Y.) had pledged to put the legislation up for a vote once the agreement is finalized.

The House of Representatives passed its own package of gun control measures in a 223-204 vote last week. Only five Republicans voted in support of the legislation, which would raise the minimum age to purchase semiautomatic rifles from 18 to 21, restrict the sale of large-capacity ammunition magazines, and set federal standards for the safe storage of firearms. The House also passed a bill to allow federal courts to temporarily confiscate guns from individuals deemed by a judge to pose a threat to themselves or others. The red flag proposal passed 224-202, with five Republicans voting in favor of the bill.

House to Kick Off Appropriations Markups This Week

Lawmakers are once again considering the use of a continuing resolution (CR) to fund the federal government beyond the end of the fiscal year (FY) on September 30, according to Senate Appropriations Ranking Member Richard Shelby (R-Ala.). Shelby went on to discuss the possibility of reaching an appropriations deal during the lame-duck session following the November midterm elections. Legislators were unable to reach a timely agreement on a bicameral spending framework, so Democrats in the House of Representatives proceeded to vote on their top-line figures so they could move to markups of the 12 annual appropriations bills for FY 2023. The House voted 217-205 to adopt a rule deeming a top-line \$1.6 trillion spending level for the fiscal year. The House Appropriations Committee recently updated its markup [schedule](#), which would see the panel acting on each of the dozen spending bills before the end of the month. Senate appropriators remain at an impasse on total defense versus non-defense spending levels, with Republicans pushing for an increase to defense spending that exceeds the rate of inflation.

Kustoff to Replace Reed on Ways and Means

Rep. David Kustoff (R-Tenn.) will replace former Rep. Tom Reed (R-N.Y.) on the House Ways and Means Committee. Kustoff will sit on three of the panel's subcommittees: Social Security, Oversight, and Worker and Family Support. Reed's spot as ranking member of the Social Security Subcommittee will be filled by Rep. David Schweikert (R-Ariz.).

Senate Confirms HHS General Counsel

The Senate confirmed Samuel Bagenstos to serve as general counsel for the U.S. Department of Health and Human Services (HHS) in a 49-43 vote last week. In this position, Bagenstos will inherit approximately 4,500 active lawsuits involving HHS, including litigation over vaccine mandates, surprise medical billing, and the 340B program. Bagenstos has served as the top lawyer for the Office of Management and Budget since January 2021. He previously worked as a disability rights attorney.

RSC Releases FY 2023 Budget Plan

The Republican Study Committee (RSC) released its 122-page fiscal year (FY) 2023 budget [plan](#) which proposes to balance the federal budget in seven years. The conservative caucus proposes to increase the eligibility age for Medicare to align with the normal retirement age for Social Security, and then index the Medicare eligibility age to life expectancy. The group calls for \$845 billion in defense spending and \$419 billion for nondefense discretionary spending in FY 2023.

National Academies Release Report on CDC's Public Health Authority

A new [report](#) from the National Academies of Sciences, Engineering, and Medicine recommends that Congress give the Centers for Disease Control and Prevention (CDC) broader authority to address threats to the public health. The report, requested by the CDC's Division of Global Migration and Quarantine, evaluates quarantine stations set up by the agency in response to the COVID-19 pandemic but also offers a wider examination of the CDC's legal and regulatory authority. The National Academies suggests that lawmakers should update the 1944 Public Health Service Act to provide more certainty around the scope and limits of CDC authority to prevent and respond to pandemics. While the bipartisan pandemic preparedness package drafted by Senate Health, Education, Labor, and Pensions Committee leadership would make changes to the CDC's operations, it does not include the National Academies' specific proposals.

WH Budgets for Next-Gen COVID Vaccines

The Biden administration will scale back several U.S. Department of Health and Human Services programs to set aside funding for the purchase of next-generation COVID-19 vaccines. The White House is allocating \$5 billion to support the purchase of new vaccine doses for a fall immunization campaign, \$4.9 billion to procure more doses of Pfizer's Paxlovid pill and \$300 million for the purchase of monoclonal antibody treatments. The administration's request for additional coronavirus response funding remains stalled before Congress.

Upcoming Congressional Hearings and Markups

Senate HELP Committee executive session to consider S. 4348, Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act, H.R. 1193, Cardiovascular Advances in Research and Opportunities Legacy Act; S. 4052, Early Hearing Detection and Intervention Act; and S. 958, Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act; 10:00 a.m.; June 14

House Energy and Commerce Subcommittee on Consumer Protection and Commerce hearing "Protecting America's Consumers: Bipartisan Legislation to Strengthen Data Privacy and Security;" 10:30 a.m.; June 14

House Appropriations Subcommittee on Defense markup of FY 2023 Appropriations; 9:30 a.m.; June 15

House Veterans' Affairs Subcommittee on Economic Opportunity hearing "Reviewing President Biden's Strategy to Reduce Veteran Suicide by Addressing Economic Risk Factors;" 9:30 a.m.; June 15

House Appropriations Subcommittee on Agriculture/Food and Drug Administration markup of FY 2023 Funding; 2:30 p.m.; June 15

Senate Finance Subcommittee on International Trade, Customs, and Global Competitiveness hearing "Supply Chain Resiliency: Alleviating Backlogs and Strengthening Long-Term Security;" the witness list can be found [here](#); 3:00 p.m.; June 15

Senate Health, Education, Labor, and Pensions (HELP) Committee hearing "An Update of the Ongoing Federal Response to COVID-19: Current Status and Future Planning;" 9:30 a.m.; June 16

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

House Appropriations markup of FY 2023 Defense Funding; 10:00 a.m.; June 23

House Appropriations markup of FY 2023 Agriculture/Food and Drug Administration Funding; 10:00 a.m.; June 23

House Appropriations Subcommittee on Labor/Health and Human Services/Education markup of FY 2023 Funding; 5:30 p.m.; June 23

House Appropriations markup of FY 2023 Labor/Health and Human Services/Education Funding; 10:00 a.m.; June 30

Recently Introduced Health Legislation

H.R.7931 — To direct the President to withdraw the United States from the Constitution of the World Health Organization, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Foreign Affairs

H.R.7936 — To amend the National Defense Authorization Act for Fiscal Year 2022 to modify the limitation on discharge of members of the Armed Forces solely on the basis of failure to obey a lawful order to receive a vaccine for COVID-19, and for other purposes; Sponsor: Rep. Johnson, Mike [R-LA-4]; Committees: House - Armed Services

H.R.7974 — To advance research, promote awareness, and provide patient support with respect to endometriosis, and for other purposes. Sponsor: Rep. Underwood, Lauren [D-IL-14]; Committees: House - Energy and Commerce

H.R.7973 — To amend the Internal Revenue Code of 1986 to provide an above-the-line deduction for the purchase of gun safes, gun safety devices, and gun safety courses. Sponsor: Rep. Stefanik, Elise M. [R-NY-21]; Committees: House - Ways and Means

H.R.7961 — To protect hospital personnel from violence, and for other purposes. Sponsor: Rep. Dean, Madeleine [D-PA-4]; Committees: House - Judiciary

H.Res.1155 — Expressing support for contraceptive rights and access in the United States and expressing the sense of the House of Representatives regarding comprehensive reproductive health care. Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Energy and Commerce; Judiciary

S.4354 — A bill to amend title 10, United States Code, regarding restrictions on the use of funds and facilities of the Department of Defense for abortion care. Sponsor: Sen. Gillibrand, Kirsten E. [D-NY]; Committees: Senate - Armed Services

S.Res.662 — A resolution expressing support for the designation of May 2022 as “Mental Health Awareness Month”. Sponsor: Sen. Lujan, Ben Ray [D-NM]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Voice Vote.

H.R.7990 — To amend the Internal Revenue Code of 1986 to temporarily expand the low-income housing tax credit for healthcare-oriented housing. Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Ways and Means

H.R.7989 — To amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods. Sponsor: Rep. Schrier, Kim [D-WA-8]; Committees: House - Energy and Commerce

H.R.7979 — To allow certain funds provided in response to the public health emergency with respect to COVID-19 to be made available for school security measures, and for other purposes. Sponsor: Rep. Miller-Meeks, Mariannette [R-IA-2]; Committees: House - Oversight and Reform

H.Res.1160 — Commending Sewa International USA and all its volunteers in chapters across America for their critical role in combating the COVID-19 pandemic in the United States, India, and several other countries. Sponsor: Rep. Fitzpatrick, Brian K. [R-PA-1]; Committees: House - Judiciary; Energy and Commerce; Foreign Affairs

S.4358 — A bill to establish an awareness campaign related to the lethality of fentanyl and fentanyl-contaminated drugs, to establish a Federal Interagency Work Group on Fentanyl Contamination of Illegal Drugs, and to provide community-based coalition enhancement grants to mitigate the effects of drug misuse. Sponsor: Sen. Murkowski, Lisa [R-AK]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.664 — A resolution expressing opposition to the criminalization of essential healthcare, including the full range of sexual and reproductive healthcare such as abortion, gender-affirming care, and contraceptive care, and disapproving of the criminalization of pregnancy outcomes. Sponsor: Sen. Duckworth, Tammy [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.8022 — To address barriers immigrants and refugees face to entering the health care workforce, and for other purposes. Sponsor: Rep. Smith, Adam [D-WA-9]; Committees: House - Energy and Commerce; Ways and Means

H.R.8021 — To authorize the Secretary of Health and Human Services to award grants to reduce barriers to immigrants becoming nurses or allied health professionals in the United States, and for other purposes. Sponsor: Rep. Smith, Adam [D-WA-9]; Committees: House - Energy and Commerce

H.R.8019 — To authorize the Secretary of Health and Human Services to award grants for career support for skilled internationally educated health professionals. Sponsor: Rep. Roybal-Allard, Lucille [D-CA-40]; Committees: House - Energy and Commerce

H.R.8014 — To amend title XIX of the Social Security Act to implement a minimum work requirement for able-bodied adults enrolled in State Medicaid programs. Sponsor: Rep. LaTurner, Jake [R-KS-2]; Committees: House - Energy and Commerce

H.R.8010 — To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to act upon pending submissions for new infant formula, to increase regulatory flexibility in the event of an infant formula shortage, and for other purposes. Sponsor: Rep. Guthrie, Brett [R-KY-2]; Committees: House - Energy and Commerce

H.R.7997 — To amend title XVIII of the Social Security Act to establish a floor in Medicare Advantage benchmark rates for regions with low Medicare fee-for-service penetration and to make the Medicare Savings Program available in all jurisdictions. Sponsor: Resident Commissioner González-Colón, Jenniffer [R-PR-At Large]; Committees: House - Energy and Commerce; Ways and Means

H.R.7995 — To amend title XVIII of the Social Security Act to exempt qualifying physicians from prior authorization requirements under Medicare Advantage plans, and for other purposes. Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Ways and Means; Energy and Commerce

H.Res.1165 — Declaring gun violence a public health crisis. Sponsor: Rep. Espaillat, Adriano [D-NY-13]; Committees: House - Energy and Commerce