



Health Policy Briefing

May 9, 2022

Senate to Vote on Abortion After Leaked Supreme Court Draft Opinion to Overturn *Roe v. Wade*

A draft Supreme Court opinion that would overturn the 1973 *Roe v. Wade* ruling was leaked to *Politico* last week. The draft majority opinion was written by Justice Samuel Alito and has preliminary support from four other Republican-appointed justices – Clarence Thomas, Neil Gorsuch, Brett Kavanaugh, and Amy Coney Barrett. The decision was drafted in February, and it is unclear whether there have been changes made since. This marks the first time in modern Supreme Court history that a draft opinion was leaked before its publication, and Chief Justice John Roberts announced that he has asked the Supreme Court’s marshal to investigate the source of the leak. The court is scheduled to rule on the case by July, considering a Mississippi law that would ban abortion after 15 weeks of pregnancy except in medical emergencies or severe fetal abnormalities.

If the opinion is finalized, each state would determine if abortion is legal within its borders. Senate Majority Leader Chuck Schumer (D-N.Y.) and House Speaker Nancy Pelosi (D-Calif.) issued a joint statement characterizing the decision as one that “would go down as...one of the worst and most damaging decisions in modern history.” President Joe Biden urged lawmakers to enshrine *Roe v. Wade* into law, as the White House has limited executive authority on this topic, and Schumer stated that the Senate will hold a vote to codify abortion rights. Democrats, however, have not outlined a clear strategy to accomplish this. Certain Democrats have called on the leadership to end the chamber’s 60-vote threshold known as the filibuster for the purposes of protecting access to abortion, but certain supporters of abortion rights, including Sens. Kyrsten Sinema (D-Ariz.), Susan Collins (R-Maine), and Lisa Murkowski (R-Alaska), oppose changes to the 60-vote threshold. And it appears unlikely that Democrats have the votes necessary to pass an abortion bill even by a simple majority. Earlier this year, a House-passed bill to codify abortion rights was blocked on a 46-48 Senate vote with Sen. Joe Manchin (D-W.Va.) siding with Republicans. A Senate vote on abortion legislation is tentatively set for Wednesday.

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Subcommittee to Markup UFA Package

Last week, the bipartisan leadership of the House Energy and Commerce Health Subcommittee released their legislative package to reauthorize the Food and Drug Administration (FDA) medical product user fee programs for the next five years. The ***Food and Drug Amendments of 2022*** (H.R.7667) was officially introduced on Friday, and the Health Subcommittee is expected to mark up the package on Wednesday, followed by full committee consideration next week. The bill would reauthorize the Prescription Drug User Fee Act, the Generic Drug User Fee Act, the Biosimilar User Fee Act, and the Medical Device User Fee Act. It also contains provisions to improve the FDA's accelerated approval pathway, increase clinical trial diversity, strengthen generic drug competition, and support the medical supply chain through FDA's inspections programs. The bill would specifically permit the FDA to remove any drugs that obtain accelerated approval from the market but fail to complete required post-market studies or fail to show a clinical benefit. The FDA would also be given the authority to require that manufacturers submit diversity action plans to incorporate diverse populations in their clinical trials. Lawmakers aim to have the package sent to the President for his signature by August. Current user fee authorizations expire on September 30. The legislative text of the reauthorization bill can be found [here](#) and a section-by-section can be found [here](#).

E&C Leadership Introduce Mental Health and Substance Use Disorder Legislation

The House Energy and Commerce Subcommittee on Health will consider a bipartisan package of mental health legislation aimed at addressing the rising number of suicides and overdose deaths in the U.S. this week. H.R. 766, the ***Restoring Hope for Mental Health and Well-Being Act of 2022*** package includes provisions to

- Establish a behavioral health crisis coordinating office within the Substance Abuse and Mental Health Services Administration (SAMHSA) and require the office to convene partners and provide technical assistance to improve access to crisis care annually;
- Reauthorize the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances and the Youth and Family TREE programs;
- Reauthorize the Garrett Lee Smith Memorial Act Suicide Prevention Program; the Maternal Mental Health Screening and Treatment Grant Program; grants to support American Indian and Alaska Native communities with mental health and substance use disorder prevention, treatment, and recovery services; and the Behavioral Health Workforce Education and Training Program;
- Require self-funded, non-federal governmental plans to comply with mental health parity laws;
- Improve the integration of evidence-based behavioral health care into primary care settings for the treatment of mental health and substance use disorders;
- Reauthorize the Pediatric Mental Health Care Access Grant Program; and
- Direct SAMHSA to assess flexibilities provided to opioid treatment programs during the COVID-19 pandemic and increase access to treatment services.

The legislative text is available [here](#) and a section-by-section can be found [here](#).

Funding for COVID Response, Ukraine Remains Stalled

Lawmakers remain at an impasse on how to get the latest tranche of COVID response funding through Congress. Republicans are opposed to attaching the \$10 billion for COVID vaccines and treatments to a package of \$33 billion in the military and humanitarian aid for Ukraine, which is viewed as must-passed legislation. The GOP, along with several Democratic lawmakers, are of the position that linking COVID funding adds uncertainty and time to the process of passing support for Ukraine's response to Russia's invasion. Negotiations have also been complicated by the Senate's shift to focus on a vote on abortion-related legislation.

China Competition Bill Moves to Conference Committee

Congress will go to a conference on the major manufacturing and innovation package (H.R. 4521) aimed at strengthening U.S. competition with China. The Senate wrapped up its series of votes on motions to instruct last week. These votes guide senators as they enter negotiations with House members to iron out the differences between the competing versions of the *United States Innovation and Competition Act*. The final piece of legislation will need to be agreed to by both chambers before it is sent to the President for his signature.

Senators Request Information About COVID-19 Pharmacy Flexibilities

Sens. Chuck Grassley (R-Iowa), Bob Casey (D-Pa.), Sherrod Brown (D-Ohio), John Barrasso (R-Wyo.), and Ben Ray Lujan (D-N.M.) sent a [letter](#) to the Centers for Medicare and Medicaid Services requesting clarification about the flexibilities that will be granted to pharmacists once the COVID-19 public health emergency (PHE) designation ends. In response to the COVID-19 pandemic, the federal government allowed pharmacists to provide testing, vaccine administration, and other services. “As HHS and CMS prepare to end the PHE, we want to ensure a smooth transition ensuring maximum regulatory flexibility under the statute. We request...CMS publish guidance about what flexibilities and clarified roles pharmacists will be able to maintain under Medicare once the PHE ends,” the senators wrote.

Wyden, Pallone Urge Compliance with Medicaid Enrollment Requirements

Senate Finance Committee Chair Ron Wyden (D-Ore.) and House Energy and Commerce Committee Chair Frank Pallone (D-N.J.) have sent [letters](#) to state contractors regarding determinations about who is eligible for Medicaid and Children’s Health Insurance Program coverage at the end of the COVID-19 public health emergency (PHE). In response to the COVID-19 pandemic, the federal government provided a Federal Medical Assistance Percentage (FMAP) increase in exchange for certain maintenance of effort requirements including maintaining continuous Medicaid enrollment for beneficiaries until the end of the COVID-19 PHE. “To protect access to health coverage for millions of eligible Medicaid beneficiaries, it is essential that contractors be held to the same level of compliance with the law as are states,” the committee chairmen wrote. “Contracts with private companies should also not be created with financial incentives that could result in eligible beneficiaries improperly losing coverage, such as contracts that increase contractor compensation based on the sheer number of individuals disenrolled.” The lawmakers request details about each company’s relationship with the state, their organizational experience working with Medicaid agencies, and information about their capacity to perform the scope of tasks they have been contracted to perform.

Baldwin Urges Passage of Workplace Violence Prevention Bill

Sen. Tammy Baldwin (D-Wis.) held a press conference last week calling on her colleagues to fast-track legislation aimed at preventing health care workplace violence. The ***Workplace Violence Prevention for Health Care and Social Service Workers Act*** ([H.R. 1195](#)) would require the Department of Labor to issue a standard for health care employers to develop workplace violence prevention plans. The bill was passed by the House of Representatives with bipartisan support in April 2021.

HIV Researcher in Lead for NIH Post

Mary Klotman, Duke University scientist and senior leader, is reportedly a lead candidate to be the next director of the National Institutes of Health (NIH). Dr. Klotman is a physician known for her research into HIV, and she has served as dean of the Duke University School of Medicine since 2017. The White House has been vetting candidates for NIH director since Francis Collins' departure in December.

Secretary of State Tests Positive for COVID

Secretary of State Antony Blinken has tested positive for COVID-19. Blinken is fully vaccinated and boosted and is only experiencing mild symptoms. According to Centers for Disease Control and Prevention guidelines, President Joe Biden is not considered a close contact with Blinken.

Upcoming Congressional Hearings and Markups

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing "Fiscal Year 2023 Budget Request for the National Institutes of Health;" 10:00 a.m.; May 11

House Appropriations Subcommittee on State, Foreign Operations, and Related Programs hearing "Fiscal Year 2023 Budget Request for U.S. Agency for International Development;" 10:00 a.m.; May 11

House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies hearing "Fiscal Year 2023 Budget Request for the National Science Foundation;" 2:00 pm.; May 11

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies hearing "Impacts of VA's Research Efforts on Veterans;" 2:00 p.m.; May 11

House Veterans' Affairs Subcommittee on Economic Opportunity hearing "Reviewing President Biden's Strategy to Reduce Veteran Suicide by Addressing Economic Risk Factors;" 2:00 p.m.; May 11

Senate Foreign Affairs Committee hearing "Review of the FY 2023 USAID Budget Request;" 2:30 p.m.; May 11

Senate Veterans' Affairs Committee hearing "Examining Quality of Care in VA and the Private Sector;" 3:00 p.m.; May 11

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing "Healthy Aging: Maximizing the Independence, Well-Being, and Health of Older Adults;" 10:00 a.m.; May 12

House Homeland Security Subcommittee on Border Security, Facilitation, and Operations hearing "Examining DHS's Efforts to Combat the Opioid Epidemic;" 2:30 p.m.; May 12

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

Recently Introduced Health Legislation

S.Res.607 — A resolution supporting the designation of the week of May 1, 2022, as “Children’s Mental Health Awareness Week” and May 5, 2022, as “Children’s Mental Health Awareness Day”; Sponsor: Sen. King, Angus S., Jr. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.613 — A resolution promoting minority health awareness and supporting the goals and ideals of National Minority Health Month in April 2022, which include bringing attention to the health disparities faced by minority populations of the United States such as American Indians, Alaska Natives, Asian Americans, African Americans, Hispanics, and Native Hawaiians or other Pacific Islanders; Sponsor: Sen. Cardin, Benjamin L. [D-MD]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.Res.614 — A resolution designating July 20, 2022, as “Glioblastoma Awareness Day”; Sponsor: Sen. Graham, Lindsey [R-SC]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4130 — A bill to repeal changes made by health care reform laws to the Medicare exception to the prohibition on certain physician referrals for hospitals, and for other purposes; Sponsor: Sen. Lankford, James [R-OK]; Committees: Senate – Finance

H.R.7640 — To amend the Orphan Drug Act to reauthorize a program of grants and contracts for the development of drugs for rare diseases and conditions (commonly referred to as “orphan drugs”); Sponsor: Rep. Bilirakis, Gus M. [R-FL-12]; Committees: House - Energy and Commerce

H.R.7646 — To amend the Federal Food, Drug, and Cosmetic Act to notify the public about an emerging signal concerning a medical device in order to reduce or limit the number of patients exposed to a potential risk identified based on such emerging signal, and for other purposes; Sponsor: Rep. Guthrie, Brett [R-KY-2]; Committees: House - Energy and Commerce

H.R.7649 — To direct the Secretary of Health and Human Services to open a public docket for the submission of public comments regarding factors that should be taken into consideration when reviewing a proposed modification to an approved risk evaluation and mitigation strategy, and for other purposes; Sponsor: Rep. Joyce, John [R-PA-13]; Committees: House - Energy and Commerce

H.R.7653 — To amend the Federal Food, Drug, and Cosmetic Act to modernize the methods of authenticating controlled substances in the pharmaceutical distribution supply chain, and for other purposes; Sponsor: Rep. Mullin, Markwayne [R-OK-2]; Committees: House - Energy and Commerce

H.R.7655 — 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

H.R.7658 — To amend the Federal Food, Drug, and Cosmetic Act to reauthorize the Critical Path Public-Private Partnerships; Sponsor: Rep. O’Halloran, Tom [D-AZ-1]; Committees: House - Energy and Commerce

S.4133 — A bill to provide for phased-in payment of Social Security Disability Insurance payments during the waiting period for individuals with a terminal illness; Sponsor: Sen. Barrasso, John [R-WY]; Committees: Senate – Finance

S.4151 — A bill to amend the Controlled Substances Act to prohibit certain acts related to fentanyl, analogues of fentanyl, and counterfeit substances, and for other purposes; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate – Judiciary

S.4152 — A bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize the Critical Path Public-Private Partnerships; Sponsor: Sen. Kelly, Mark [D-AZ]; Committees: Senate - Health, Education, Labor, and Pensions