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State of Infrastructure and Reconciliation Negotiations

The past month saw few developments on the revival of a reconciliation bill as the Senate focused their attention on President Biden's Fiscal Year 2023 budget request and Senator Joe Manchin (D-WV) held discussions on a potential bipartisan energy package. While a health focused partisan reconciliation bill, the most likely vehicle for any significant drug pricing reform, remains possible, Senator Manchin's convening of a bipartisan group for an energy package further pushes the effort down the legislative road. With Congress' time taken up by China competitiveness legislation, a bipartisan energy package, and other must-pass efforts, the likelihood of a reconciliation package becomes increasingly smaller. Should negotiations not pick up before the Memorial Day recess, it is unlikely that a reconciliation package can be ushered through Congress before the September 30 deadline.

House Republicans Release New Health Platform

On May 2, 2022, House Republicans released a new health policy platform. The platform is an effort to lower out-of-pocket spending and provide greater access to new medicines and cures. To do this, Republicans will focus on removing government interference and bureaucrats from the American healthcare system. Additionally, Republicans are promoting American-made medicines so that patients and cures will no longer be "held hostage by supply chain disruptions or foreign government restrictions."

View the 1-pager [HERE](#).

Appropriations Update

The fiscal year 2023 appropriations process is currently in full swing with House and Senate Appropriations Committees holding hearings on President Biden's fiscal year 2023 proposed budget. If history is any indicator, the House Appropriations Committee will release their own versions of appropriations legislation this summer with hearings, markups, and ultimate passage to follow. The Senate, on the other hand, tends to move rather slowly when compared to the House. In fiscal year 2022, the Senate only released draft legislation and did not go through the traditional legislative process.

Democrats in Congress are likely going to push for a deal to be reached between the House and the Senate before the midterm elections, as they would like to score a legislative victory while also showing the American people that they can effectively operate the government. However, with a 50-50 Senate, Democrats will need at least 10 Republicans to join them in funding the government, something that is increasingly unlikely the closer we get to the midterms. As time passes without significant movement from the Senate, it is more and more likely that a short-term continuing resolution will be needed in order to keep the government funded and operating.

FDA User Fee Reauthorization Package

On May 4, 2022, the House Energy and Commerce Committee released their bipartisan FDA User Fee Reauthorization Package. The package, unveiled by Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ), Ranking Member Cathy McMorris Rodgers (R-WA), Health Subcommittee Chairwoman Anna G. Eshoo (D-CA), and Health Subcommittee Ranking Member Brett Guthrie (R-KY), reauthorizes the Prescription Drug User Fee Act (PDUFA), the Generic Drug User Fee Act (GDUFA), the Biosimilar User Fee Act (BsUFA), and the Medical Device User Fee Act (MDUFA). The legislative package includes provisions that will:

- Make improvements to FDA's review for safety and efficacy of medical products, including cell and gene therapies, drugs for rare diseases, and novel medical devices;
- Strengthen program integrity for the Accelerated Approval pathway and preserve patient access to approved treatments by ensuring that drugs show clinical benefit through post-approval studies in a timely manner and streamline the process for withdrawing approvals for drugs that fail to show a clinical benefit;
- Ensure clinical trials are representative of diverse populations by requiring drug and medical device manufacturers to submit clinical trial diversity action plans to FDA early in their development process;
- Bring down drug costs by making it easier for generic competition to enter the market; and
- Provide FDA tools to ensure the agency can conduct thorough safety inspections efficiently.

As of now, the Senate Health, Education, Labor, and Pensions Committee has yet to release their version of the reauthorization. However, the release of the House package is significant as it starts the process towards reauthorization, which currently expires on September 30, 2022.

View legislative text [HERE](#).

View section-by-section [HERE](#).

Senate Health, Education, Labor and Pensions Committee Hearing

“FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, FDA Center Directors”

April 26, 2022

Witnesses

Patrizia Cavazzoni, M.D.

Director

Center for Drug Evaluation and Research, United States Food and Drug Administration

Silver Spring, MD

Peter Marks, M.D., Ph.D

Director

Center for Biologics Evaluation and Research, United States Food and Drug Administration

Silver Spring, MD

Jeffrey Shuren, M.D., J.D.

Director

Center for Devices and Radiological Health, United States Food and Drug Administration

Silver Spring, MD

Summary

On April 26, 2022, the Senate HELP committee held the second of two hearings to discuss the reauthorization of four Food and Drug Administration (FDA) User Fee Programs. The four programs up for discussion in the hearing were the Prescription Drug User Fee Agreement-7th version (PDUFA-7), the Generic Drug User Fee Agreement-3rd version (GDUFA-3), the Medical Device User Fee Agreement-5th version (MDUFA-5), and the Biosimilar User Fee Agreement (BsUFA). Both Democrats and Republican’s voiced their complaints to the FDA on a wide variety of issues including FDA’s response to goals set by the current User Fee Agreements, the controversy over the FDA’s involvement with the consulting company McKinsey, and other FDA shortcomings.

In her opening statement Chairwoman Patty Murray (D-WA) expressed her concern for the slow response by the FDA to heavy metals found in baby food, and the withdrawal of contaminated baby food from consumers. She stated that people depend on the FDA and put their wellbeing in their hands, that these programs ensure the FDA has more drug options to consider for approval, and the resources to do so. She spoke of learning from the pandemic challenges and beyond to address what is and is not working within these programs. She also issued goals of her own she hopes can be accomplished with these programs including, diversifying trials, lowering drug costs, capping insulin at \$35 dollars a month, and creating steps for the FDA to make good on the promise of a law to allow hearing aids to be sold over the counter. She also stated she would like to see FDA oversight of items such as cosmetics, child makeup kits, and dietary supplements that make claims without any safety regulation.

Ranking Member Richard Burr (R-NC) opened by expressing the importance of the FDA to keep pace with medical advancement. He emphasized the importance for the programs, and the FDA to be held accountable to Congress and the American people. He stated that the swift action of the FDA to attack the pandemic should not be the exception but the rule, and the same urgency should be applied to the diagnosis of cancer, and Alzheimer's disease. He also pointed out that the FDA has the responsibility to meet the terms of the User Fee Agreements. He went on to discuss his involvement in past User Fee regulation starting in 1997. He expressed concern for the FDAs missed goals, stating that he knows the FDA can do better and hopes that the panelists can prove to him that they are on the right tract. He believes that the User Agreements up for discussion can be signed into law if more accountability is brought into the programs.

Dr. Cavazzoni, made it clear that the GDUFA could and does provide generic drugs to patients, and that the savings have positively impacted U.S families. To put more generic drugs on the market there is a need for effective and efficient FDA approval. She stated that together the GDUFA-3 and BsUFA will save developers time and resources and hopefully lower healthcare costs. Within the new programs there are proposals to retain performance goals and improve communication between the developers of drugs and the FDA. She finished by emphasizing the critical importance of passing the programs.

Dr. Marks opened his statement by stating that since the first enactment of the PDUFA there has been a reversal in the lag in approval and more timely access for patients to prescription drugs. PDUFA-7 will shorten review times and enhanced interactions and improve potential for first cycle drug approvals. He stated that the focus of PDUFA-7 is on applied scientific research, enhancement and modernization, manufacturing technology, and talent recruitment. He went on to discuss the achievements of the FDA in the Regenerative Medicine Advanced Therapy (RMAT) Designation, stating that since December of 2016, 72 of 187 requests have received RMAT designation three of which have received approval in 2021. These included two gene cellular products, one for children with a rare immunity disorder, one for wound healing, and one for CAR-T cell therapy for patients with B-Cell Lymphoma.

Dr. Shuren began his statement with regrets that the FDA missed multiple statutory deadlines to Congress, stating that thoughtful agreements can increase the accountability for the programs and exceed goals in the future. The MDUFA received an increase in work load and submissions for which they were not fully funded. He stated that during the pandemic the Center for Devices and Radiological Health (CDRH) granted emergency use authorization for nearly 2300 medical devices for Covid-19, including over 460 tests and self-collection kits. Because of the overwhelming increase in submissions, there has been a backlog in approvals for devices causing the CDRH to fall short of some of their MDUFA-4 goals. He pointed to MDUFA-5's proposal that addresses resource gaps and provides improved support performance and accountability mechanisms such as add on payments. He also took the time to point out the voluntary pilot program, Total Product Life Cycle Advisory Program (TAP), that will increase involvement with sponsors of breakthrough devices.

Chairwoman Murray asked questions regarding both the wait for a Covid-19 vaccine for young children and the work being done to address the opioid crisis. She then turned it over to Ranking Member Burr who took the time to point out the 260 job vacancies at the FDA and asked how PDUFA can allow them to meet their hiring goals.

Senator Hassan (D-NH) asked what the FDA response is to the consulting company McKinsey failing to notify them of their conflicts of interest before undergoing contracting with the FDA, to which Dr. Cavazzoni replied that there are no current contracts with McKinsey and no further contracts intend to be issued at this moment. Senator Rosen (D-NV) took the time to note the importance of cybersecurity in the healthcare system and voiced concern for the level of security pertaining to medical devices at the FDA. She also inquired how the FDA implements academic partnerships into their research, particularly with universities such as UNLV.

In closing remarks Senator Burr voiced his concerns of Dr. Shuren's proposal for the TAP program under MDUFA-5, explaining that he feels it is unnecessary given the current capabilities already set in place to operate in the same function in which he is proposing. He finished by stating that we need private capital chasing the next biomedical technology, biomedical investments are at the lowest points we've seen. This path is the door to the next cancer solution, he explained that private investment is how a whole new category of cancer research was founded at the NIH.

Up to Date List of Drug Related Legislation for the 117th Congress

- [H.R. 7669](#)
This bill, introduced on 5/6/2022 by Rep. Doris Matsui (D), requires guidance on extending expiration dates for certain drugs, and for other purposes.
- [H.R.7472 - Discounted Drugs for Clinical Trials Act](#)
This bill, introduced by Rep. Carolyn Maloney (D-NY) on April 7, 2022, amends amend the Federal Food, Drug, and Cosmetic Act to grant eligible researchers access to eligible products at a discounted price for qualified research, and for other purposes.
- [H.R. 7640](#)
This bill, introduced by Rep. Gus Bilirakis (R-FL) on 5/3/2022, amends 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").
- [H.R.7473](#)
This bill, introduced on 04/07/2022 by Rep. Carolyn B. Maloney (D-NY-12), works to prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.
- [S.3991](#)
This bill, introduced 04/05/2022 by Sen. Tina Smith (D-MN), works to direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.
- [H.R.7032](#)
The Bill, introduced 03/09/22 by Rep. Ann M. Kuster is increases Transparency in Generic Drug Applications Act of 2022, amending section 505(j) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(j)) with respect to a process to inform persons submitting an abbreviated application for a new drug whether the new drug is qualitatively or quantitatively the same as a listed drug, and for other purposes.

- [H.R. 7474](#)
Introduced 04/07/2022 by Rep. Carolyn B. Maloney, the bill amends the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes.
- [S.4037](#)
Introduced 04/07/2022 by Sen. Debbie Stabenow (D-MI). The bill amends the Public Health Service Act to increase the transparency of pharmaceutical research costs, and for other purposes.
- [H.R. 7400](#) - American Made Pharmaceuticals Act of 2022
The bill, introduced 04/05/2022 by Rep. Angie Craig (D-MN-2), created to direct the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.
- [H.R. 7121](#) - Protecting our Pharmaceutical Supply Chain from China Act of 2022
Introduced 03/17/2022 by Rep. Mike Gallagher (R-WI-8). A bill to require the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China, and for other purposes.
- [H.R. 6875 – Right Drug Dose Now Act](#)
This bill introduced on 02/28/2022 by Rep. Eric Swalwell [D-CA-15], is to update the National Action Plan for Adverse Drug Event Prevention to provide educational information on adverse drug events and pharmacogenomic testing, to improve electronic health records for pharmacogenomic information, and for other purposes.
- [H.R. 6834 – Recall Unsafe Drugs Act of 2022](#)
The bill, introduced on 02/25/2022 by Rep. Rosa L. DeLauro [D-CT-3], will provide the mandatory recall of drugs regulated by the Food and Drug Administration.
- [H.R. 6833 – Affordable Insulin Now Act](#) and [S.3700](#)
The bill, introduced in the Senate on 02/17/2022 by Sen. Raphael G. Warnock [D-GA] and in the House on 02/25/2022 by Rep. Angie Craig [D-MN-2], will amend title XXVII of the Public Health Service Act, the Internal Revenue Code of 1986, and the Employee Retirement Security Act of 1974 to establish requirements with respect to cost-sharing for certain insulin products.
- [H.R. 6757 – Insulin Savings for Patients Act](#)
The bill, introduced on 02/18/2022 by Rep. Michael C. Burgess [R-TX-26] will amend title XVIII of the Social Security Act to establish under the Medicare prescription drug program

a minimum amount of price concessions for insulin to be passed through to beneficiaries at the point-of-sale.

- [H.R. 6710](#)
Introduced by Rep. Yvette Herrell [R-NM-2] on 02/11/2022, the bill will direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices.
- [S. 3615 – Cutting Medicare Prescription Drug Prices in Half Act](#)
The bill, introduced by Sen. Bernard Sanders [I-VT] on 02/09/2022, will establish a cap on costs for covered prescription drugs under Medicare parts B and D.
- [S. 3493 - Drug Shortages Shelf Life Extension Act](#)
This bill, introduced by Sen. Ben Cardin (D-MD) on January 12, 2022, requires guidance on extending expiration dates for certain drugs, and for other purposes.
- [H.R. 6483 - Improved Transparency of Foreign Drug Manufacturing Act of 2022](#)
This bill, introduced by Rep. Anna Eshoo (D-CA) on January 25, 2022, amends the Federal Food, Drug, and Cosmetic Act to clarify reporting requirements for establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an active pharmaceutical ingredient, and for other purposes.
- [S. 3576](#)
This bill, introduced by Sen. Mike Braun (R-IN) on February 3, 2022, allows sponsors of certain new drug applications to rely upon investigations conducted in certain foreign countries, and for other purposes.
- [H.R. 6584](#)
This bill, introduced by Rep. Anna Eshoo (D-CA) on February 3, 2022, directs the Commissioner of Food and Drugs to amend certain regulations to increase clinical trial diversity, and for other purposes.
- [S. 3449](#)
This bill, introduced by Sen. Gary Peters (D-MI) on January 10, 2022, requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to register with the Food and Drug Administration regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported into the United States.
- [S. 3401 – ABC Safe Drug Act](#)
This bill, introduced by Sen. Tom Cotton (R-AR) on December 15, 2021, requires the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China, and for other purposes.

- [S.3339 - Capping Prescription Costs Act of 2021](#)
This bill, introduced by Sen. Raphael Warnock (D-GA) on December 8, 2021, limits cost sharing for prescription drugs, and for other purposes.
- [H.R.6101 - Drug Price Transparency in Medicaid Act of 2021](#)
This bill, introduced by Rep. Buddy Carter on December 1, 2021, amends title XIX of the Social Security Act to improve transparency and prevent the use of abusive spread pricing and related practices in the Medicaid program.
- [H.R.5872](#)
This bill, introduced by Rep. Sean Patrick Maloney (D-NY) on November 4th, 2021, amends the Federal Food, Drug and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the cosmetic meets certain standards , and for other purposes.
- [S.3080](#)
This bill, introduced by Senator Tina Smith (D-MN) on October 27, 2021, amends the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide for cost-sharing for oral anticancer drugs on terms no less favorable than the cost-sharing provided for anticancer medications administered by a health care provider.
- [H.R.5632](#)
This bill, introduced by Rep. Kurt Schrader (D-OR) on October 19, 2021, establishes a statutory definition for long-term care pharmacy under the Medicare prescription drug benefit.
- [H.R.5576](#)
This bill, introduced by Rep. Susan Wild (D-PA) on October 12, 2021, allows states to apply the requirements of the Medicaid Drug Rebate Program to covered outpatient drugs under the Children's Health Insurance Program (CHIP).
- [H.R.5463](#)
This bill, introduced by Rep. Matthew Rosendale (R-MT) on September 30, 2021, increases reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes.
- [H.R.5237](#)
This bill, introduced by Rep. Scott Peters (D-CA) on September 10, 2021, amends titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.
- [S. 2595](#) - Drug Shortages Prevention and Quality Improvement Act

This bill, introduced by Senator Ben Cardin (D-MD) on August 4, 2021, address prescription drug shortages and improve the quality of prescription drugs, and for other purposes.

- [H.R. 4991](#) - Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2021
This bill, introduced by Rep. Peter DeFazio (D-OR) on August 10, 2021, requires persons who undertake federally funded research and development of a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.
- [H.R. 5099](#) - Lowering Medicare Premiums and Prescription Drug Costs Act
This bill, introduced by Rep. Bradley Schneider (D-IL) on August 24, 2021, amends title XVIII of the Social Security Act to move Medicare cost-sharing benefits from Medicaid to Medicare, and for other purposes.
- [H.R. 3662](#)
This bill, introduced by Rep. Morgan Griffith (R-VA) on June 1, 2021, amends the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain urgent-use compounded medications, and for other purposes.
- [H.R. 3761](#)
This bill, introduced by Rep. Mike Gallagher (R-WI) on June 8, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.
- [H.R. 3927](#) and [S. 2082](#)
This bill, introduced by Rep. Buddy Carter (R-GA) and Sen. Tim Scott (R-SC) on June 16, 2021, mitigates drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical diagnostic devices, pharmaceuticals, and personal protective equipment in the United States, and for other purposes.
- [S. 2257](#)
This bill, introduced by Sen. Jacky Rosen (D-NV) on June 24, 2021, provides Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.
- [S. 2304](#)
This bill, introduced by Sen. Dick Durbin (D-IL) on June 24, 2021, amends title XI of the Social Security Act to require that direct-to-consumer advertisements for prescription drugs and biological products include an appropriate disclosure of pricing information.
- [H.R. 4121](#)
This bill, introduced by Rep. Jody Arrington (R-TX) on June 24, 2021, codifies a final rule issued by the Secretary of Health and Human Services relating to fraud and abuse and the removal of safe harbor protection for certain drug rebates, and for other purposes.

- [H.R. 4158](#)
This bill, introduced by Rep. Bobby Rush (D-IL) on June 24, 2021, amends titles XVIII and XIX of the Social Security Act to eliminate cost sharing with respect to coverage of insulin as a covered part D drug under the Medicare program or as a covered outpatient drug under the Medicaid program.
- [H.R. 4287](#)
This bill, introduced by Rep. Greg Murphy (R-NC) on June 30, 2021, directs the Comptroller General of the United States to conduct a study on how direct-to-consumer pharmaceutical advertising negatively impacts drug costs to consumers, and for other purposes.
- [S. 1644](#)
This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.
- [S. 1645](#)
This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, provides for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.
- [H.R. 3203](#)
This bill, introduced by Rep. Doris Matsui (D-CA) on May 13, 2021, enables certain hospitals that were participating in or applied for the drug discount program under section 340B of the Public Health Service Act prior to the COVID-19 public health emergency to temporarily maintain eligibility for such program, and for other purposes.
- [S. 1773](#)
This bill, introduced by Sen. Bob Casey (D-PA) on May 20, 2021, amends title XI of the Social Security Act to establish internet website-based dashboards to allow the public to review information on spending for, and utilization of, prescription drugs and biologicals covered under the Medicare and Medicaid programs.
- [H.R. 3437](#)
This bill, introduced by Rep. Bobby Rush (D-IL) on May 20, 2021, requires the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.
- [H.R. 2344](#)
This bill, introduced by Rep. Tim Ryan (D-OH) on April 1, 2021, requires the use of prescription drug monitoring programs.
- [H.R. 2484](#)

This bill, introduced by Rep. Katie Porter (D-CA) on April 13, 2021, amends title XXVII of the Public Health Service Act and title XVIII of the Social Security Act to require pharmacies to disclose any differential between the cost of a prescription drug based on whether certain individuals use prescription drug coverage to acquire such drug, and for other purposes.

- [S. 1124](#)

This bill, introduced by Sen. Marsha Blackburn on April 14, 2021, preserves non-interference under the Medicare part D Prescription Drug Benefit program.

- [H.R. 2608](#)

This bill, introduced by Rep. Peter Welch (D-VT) on April 15, 2021, amends title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes.

- [H.R. 2623](#)

This bill, introduced by Rep. Josh Gottheimer (D-NJ) on April 16, 2021, amends the Internal Revenue Code of 1986 to restore the amount of the orphan drug tax credit, and for other purposes.

- [H.R. 2706](#)

This bill, introduced by Rep. Katie Porter (D-CA) on April 20, 2021, amends title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.

- [H.R. 2829 and S. 1323](#)

This bill, introduced by Rep. Peter Welch (D-VT) and Sen. Jeff Merkley (D-OR) on April 22, 2021, requires the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

- [S. 1366](#)

This bill, introduced by Sen. Elizabeth Warren (D-MA) on April 26, 2021, secures the supply of drugs in the United States, and for other purposes.

- [H.R. 2846](#)

This bill, introduced by Rep. David McKinley (R-WV) on April 27, 2021, amends title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

- [H.R. 2853](#)

This bill, introduced by Rep. Kurt Schrader (D-OR) on April 27, 2021, amends the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

- [S. 1425](#)
This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.
- [S. 1428](#)
This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, prohibits brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.
- [H.R. 2868](#)
This bill, introduced by Rep. G.K. Butterfield (D-NC) on April 28, 2021, amends title XIX of the Social Security Act to prohibit additional rebates under the Medicaid program for certain noninnovator multiple source drugs.
- [H.R. 2870](#)
This bill, introduced by Rep. Buddy Carter (R-GA) on April 28, 2021, amends the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.
- [H.R. 2883](#)
This bill, introduced by Rep. Hakeem Jeffries (D-NY) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.
- [H.R. 2891](#)
This bill, introduced by Rep. Jerry Nadler (D-NY) on April 28, 2021, prohibits prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.
- [S. 1462](#)
This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.
- [S. 1463](#)
This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to modernize therapeutic equivalence rating determinations.
- [S. 1508](#)

This bill, introduced by Sen. Roger Marshall (R-KS) on April 29, 2021, provides for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

- [S. 1523](#)
This bill, introduced by Sen. Mike Braun (R-IN) on April 29, 2021, amends title XI of the Social Security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits.
- [H.R. 2148](#)
This bill, introduced by Rep. Ro Khanna (D-CA) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.
- [S. 909](#)
This bill, introduced by Sen. Bernie Sanders (I-VT) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.
- [S. 898](#)
This bill, introduced by Sen. Tammy Baldwin (D-WI) on March 23, 2021, requires reporting regarding certain drug price increases, and for other purposes.
- [S. 833](#)
This bill, introduced by Sen. Amy Klobuchar (D-MN) on March 18, 2021, amends XVII of the Social Security Act to allow the Secretary of Health and Human Services to negotiate fair prescription drug prices under part D of the Medicare program.
- [H.R. 597](#)
This bill, introduced by Rep. Jan Schakowsky (D-IL) on January 28, 2021, requires any COVID-19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, and for other purposes.
- [S. 141](#)
This bill, introduced by Sen. Jeanne Shaheen (D-NH) on January 28, 2021, amends the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.
- [H.R. 153](#)
This bill, introduced by Rep. Bobby Rush (D-IL) on January 4, 2021, prohibits brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

In The News

[Politico](#) (5/6/2022): **HOUSE E&C COMMITTEE REVEAL THE FOOD AND DRUG AMENDMENTS OF 2022** — Lawmakers on the House Energy and Commerce Committee released bipartisan legislation that would reauthorize FDA medical product user fee programs for another five years, David and Katherine report. Congress must periodically reauthorize the programs to continue to allow FDA to collect fees from the medical product manufacturers, which it uses to hire staff to review product applications more expeditiously.

[Modern Healthcare](#) (5/6/2022): **Hospitals see growing financial impact from 340B discount restrictions** - Hospitals expect median annual losses of \$2.2 million due pharmaceutical companies limiting 340B drug discounts, according to a survey.

[Bloomberg](#) (5/5/2022): **Kids' Cancer Research Bill to Get Push in FDA Fee Plan Talks** - Policy advocates and lawmakers are aiming to get several bills added into a must-pass FDA user fee package after proposals to boost pediatric cancer treatment research and improve oversight on diagnostic tests were left out of an initial version.

[Modern Healthcare](#) (5/6/2022): **Cigna launches digital cancer consult service** - The service will be expanded to include more customers of both Cigna and its Evernorth eviCore analytics platform.

[Axios](#) (5/5/2022): **The trouble with telehealth prescriptions** - Mental telehealth startups such as Cerebral and Done Health are coming under increased scrutiny for the way they prescribe drugs with a high potential for abuse like Adderall.

[Bloomberg](#) (5/5/2022): **New Cancer Drug Access at Risk in Oregon Medicaid Proposal**: An Oregon proposal to exclude expensive drugs that received FDA fast-track approval from Medicaid coverage is alarming advocates for patients with cancer and other life-threatening diseases. If approved, the proposal could limit access in Medicaid to promising treatments for patients with deadly conditions, and could encourage other states to similarly attempt to restrict access to get relief from rising drug costs, advocates say.

[Bloomberg](#) (5/5/2022): **Lawmakers Seek to Boost FDA Power Over Fast-Tracked Drugs**: The FDA could remove from the market any drugs that obtained accelerated approval if they fail to show a clinical benefit under a proposed package reauthorizing must-pass user fee legislation. The bipartisan proposal, unveiled Wednesday by leaders of the House Energy and Commerce Committee, would push sponsors of drugs approved through the accelerated pathway to complete required postmarket studies. Both the Food and Drug Administration and lawmakers have pushed for legislative changes to minimize the amount of time between when an accelerated approved drug enters the market and its clinical benefit is confirmed.

[Politico](#) (5/5/2022): **HOUSE E&C COMMITTEE UNVEILS FDA USER FEE PACKAGE** — On Wednesday, top lawmakers on the House Energy and Commerce Committee published bipartisan

legislation that would reauthorize the FDA's medical product user fee programs, David and POLITICO's Katherine Ellen Foley report.

[Politico](#) (5/3/2022): **GOP UNVEILS NEW HEALTH PLATFORM** — The House GOP Healthy Future Task Force on Friday debuted a one-page policy platform that diverges significantly from certain Trump-era proposals like international price indexing. But it keeps some familiar proposals favored by the drug industry like having health plans share drug discounts with patients at the pharmacy counter and device-industry priorities like speeding Medicare coverage for breakthrough medical devices.

[Axios](#) (5/3/2022): **GOP dialing back its drug price goals** - House Republicans are dialing back their drug pricing goals and abandoning direct government negotiations and other signature policies from the Trump years, Adriel writes.

[Politico](#) (5/3/2022): **WICKER PRESSES BIDEN ADMIN TO FILL OSTP DIRECTOR POSITION** — Sen. Roger Wicker (R-Miss.), the Commerce Committee's ranking member, urged the Biden administration on Monday to fill the top leadership position at the White House Office of Science and Technology Policy. Sociologist Alondra Nelson stepped in to carry out director duties after Eric Lander resigned in February amid reports of bullying, though it's not a permanent role.

[Politico](#) (5/3/2022): **CMS RULE TO LOWER COST-SHARING BURDEN AT PHARMACIES** — CMS released a final rule Friday for the Medicare Advantage and Part D prescription drug programs, aiming to lower out-of-pocket costs for beneficiaries. The rule would require Part D plans "to apply all price concessions they receive from network pharmacies to the negotiated price at the point of sale, so that the beneficiary can also share in the savings."

[Politico](#) (5/3/2022): **ADVOCACY GROUPS MAKE FRESH PUSH FOR DRUG PRICE REFORM** — The group Patients for Affordable Drugs is launching a new, six-figure ad campaign to push the Senate to restart efforts on Medicare negotiation of drug prices, inflation caps and other cost controls the House passed last year and advance a bill by Memorial Day.

[Bloomberg](#) (5/2/2022): **ARPA-H Faces Pressure on Drug Patent Grabs** - NIH could find itself wading into the drug pricing debate as it houses a new biomedical accelerator, despite its longstanding policy not to get involved in the cost of new therapies.

[Politico](#) (4/29/2022): **ESHOO WEIGHS IN ON USER FEE REAUTHORIZATION RIDERS** — Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-Calif.) told POLITICO on Thursday it is still her preference that "there wouldn't be anything attached" to the FDA user fee program reauthorization package but acknowledged Congress is "not there yet."

[Modern Healthcare](#) (4/29/2022): **MD Anderson partners with Community Health Network on integrated cancer program** - The partnership gives Community Health Network physicians access to MD Anderson experts and patients access to innovative cancer treatments, clinical trials and research studies.

[Politico](#) (4/29/2022): **CMS: WE WILL CONTINUE TO COVER ACCELERATED APPROVAL DRUGS** — CMS expects it will continue to cover accelerated approval drugs, CMS Administrator Chiquita

Brooks-LaSure said Thursday at a Q&A hosted by the Association of Health Care Journalists in Austin, Texas, POLITICO's Alice Miranda Ollstein reports.

[Bloomberg](#) (4/28/2022): **Eshoo Pledges ARPA-H Independence From NIH**: A debate over where a new biomedical accelerator agency should sit within the federal government isn't over, as a top health lawmaker said she'll keep working to keep the new office outside of the NIH. "Congress authorizes. Congress appropriates," Rep. Anna Eshoo (D-Calif.), chair of the House Energy and Commerce Health Subcommittee, said at a hearing on the Health and Human Services Department's budget request. Eshoo said that HHS Secretary Xavier Becerra "has his view. I don't agree with it. So I will present authorizing legislation."

[Politico](#) (4/28/2022): **DEMS REIGNITE MEDICAID EXPANSION EFFORT** — Rep. Carolyn Bourdeaux (D-Ga.) and Sen. Raphael Warnock (D-Ga.) on Wednesday relaunched an effort to include Medicaid expansion in the reconciliation package.

[Axios](#) (4/28/2022): **Hospitals press for more federal aid as fortunes turn** - Hospitals' financial fortunes have taken a turn for the worse in recent weeks, thanks to less-than-favorable Medicare policies and rising labor and supply costs, Axios' Adriel Bettelheim and Caitlin Owens write.

[Bloomberg](#) (4/27/2022): **Manchin Sees Drug Price Path to Skirt GOP** - Key holdout Sen. Joe Manchin (D-W.Va.) said on Tuesday he discussed a tax increase and deficit reduction bill with Senate Majority Leader Chuck Schumer (D-N.Y.) as a way to fight soaring inflation, and said it would make sense to include cuts to prescription drug prices in the measure.

[Modern Healthcare](#) (4/27/2022): **Telehealth didn't lead to unnecessary care in 2020, study says** - The research refutes concerns that telehealth could lead to duplicative care.

[Politico](#) (4/27/2022): **REPEAL AND REPLACE IS OVER, REFORM IS NOT** — With Republicans poised to resurge in Congress, one question looms large: Where does the GOP stand today on the Affordable Care Act?

[Politico](#) (4/26/2022): **FDA CENTER DIRECTOR DERBY** — The leaders of FDA's drug, biologic and medical device centers are testifying before the Senate HELP Committee this morning on user fee agreements.

[Bloomberg](#) (4/26/2022): **FDA User Fee Agreements**: The Senate Health, Education, Labor, and Pensions Committee holds another hearing on user fee agreements between the Food and Drug Administration and the medical industry, which are being negotiated ahead of legislation that would enshrine them into law. Today's session includes three directors of FDA centers. For more on the authorization legislation, see the BGOV OnPoint: Congress Ramps Up for FDA User Fee Reauthorization.

[Politico](#) (4/26/2022): **FDA GOES TO WASHINGTON PART TWO** — Commissioner Robert Califf will take over the mantle of congressional testimony from his deputies later this week; the FDA chief is scheduled to testify on his agency's fiscal 2023 budget ask before the Senate Appropriations Agriculture Subcommittee on Thursday. He was also scheduled to appear before the House Appropriations Agriculture Subcommittee on Wednesday, but that hearing has been postponed, per the committee website.

[Bloomberg](#) (4/26/2022): **Lobbying Effort to Lower Drug Prices Launches**: Long-time supporters of legislation to allow the government to demand drugmakers lower their prices will announce today the launch of a new campaign to reenergize Democrats' stalled effort to pass a sweeping domestic agenda before the end of May.

[Politico](#) (4/25/2022): **FIRST IN PULSE: WARREN PRESSES BIDEN ADMIN TO ACT ON DRUG PRICING AMID HILL STALEMATE** — Sen. Elizabeth Warren (D-Mass.) wrote to HHS Secretary Xavier Becerra today outlining a set of executive actions the Biden administration can take without Congressional approval to lower drug prices and pushing for action given the current impasse on the issue on Capitol Hill.

[Axios](#) (4/25/2022): **Ukraine aid could boost prospects for COVID package** - President Biden's call for more Ukraine aid could provide the groundwork for reviving a \$10 billion COVID preparedness package that's stalled in Congress — if Democrats can tamp down their internal divisions, Axios' Adriel Bettelheim writes.

[Modern Healthcare](#) (4/25/2022): **Study mines cancer genetics to help with targeted treatment** - Researchers identified 58 new clues to the causes of cancer called "mutational signatures" that contribute to the development of the disease.

[Politico](#) (4/22/2022): **HELP COMMITTEE TEES UP USER FEE HEARING WITH FDA OFFICIALS** — The Senate Health Committee will hold a hearing on FDA user fee agreements on Tuesday morning. CDER Director Patrizia Cavazzoni, CBER Director Peter Marks and CDRH Director Jeff Shuren are set to testify.

[Axios](#) (4/22/2022): **Drug lobby taps Biden aide's brother** - Jeff Ricchetti, the brother of senior White House official Steve Ricchetti, has been lobbying for the drug industry's top trade group, Axios' Lachlan Markey reports.

[Politico](#) (4/21/2022): **LOOMING LOSS OF TELEHEALTH ACCESS** — Millions of patients are losing expanded access to telehealth across state lines as states' pandemic emergency declarations wind down, POLITICO's Ben Leonard writes.

[Modern Healthcare](#) (4/21/2022): **Surprise bill resolutions' path forward hinges on final rule** - With the dispute resolution portal open, making further changes to the process could be difficult.

[Politico](#) (4/20/2022): **STATE OF TELEHEALTH** — The telehealth industry, which has grown tremendously amid the pandemic, faces some uncertainty as more states end waivers allowing care across state lines.

[Axios](#) (4/19/2022): **Hospitals' massive cancer drug markups** - The prices that private insurers agree to pay hospitals for cancer drugs are often at least double what the hospital paid to acquire the drugs, Axios' Caitlin Owens reports from a new study in JAMA Internal Medicine.

[The Hill](#) (4/18/2022): **FTC's inquiry of PBMs won't lower prescription drug costs** - I recently had the opportunity to participate in a listening forum at the Federal Trade Commission (FTC) on competition in the health care industry where I shared my thoughts on what needs to be done to

make prescription drugs more affordable — a goal we firmly support. During the session, I also expressed my concern that the FTC seems to be choosing to single out the only actors in the pharmaceutical supply chain whose fundamental role is to negotiate lower drug prices for patients — pharmacy benefit managers, PBMs. I encouraged the commissioners to seek to understand the broader prescription drug marketplace with a focus on what ultimately best serves consumers.

[Politico](#) (4/8/2022): **SENATE PUNTS VOTE ON NEW COVID FUNDS** — Democrats are again postponing an effort to pass legislation that would allow for \$10 billion to be spent on Covid-19 therapeutics, vaccines and tests until after the Senate returns from a two-week spring break, Alice reports . Top Biden administration officials have repeatedly warned that a delay in new funding threatens the country’s ability to fight the virus and prepare for potential surges and variants.

[Bloomberg](#) (4/8/2022): **Lawmakers Seek Public Drug Clinical Trial Cost Report:** A group of congressional Democrats including House Oversight and Reform Chair Carolyn Maloney (D-N.Y.), as well as Sens. Debbie Stabenow (D-Mich.) and Tina Smith (D-Minn.), introduced legislation Thursday requiring drug manufacturers to publicly disclose clinical trial costs. The legislation is part of a slew of bills seeking to lower drug costs, the lawmakers said. These bills “target Big Pharma’s manipulative practices in order to strengthen competition, promote innovation, and increase transparency,” Maloney said, Se Young Lee reports.

[Politico](#) (4/8/2022): **HOUSE DEMS PUT FORWARD MORE DRUG PRICING BILLS AMID BBB STALEMATE** — Democrats on the House Oversight Committee introduced a package of three bills Thursday aimed at lowering drug prices as pharmaceutical reforms in the Build Back Better legislation languish in the Senate, Alice reports. The bills, which the committee crafted based on the results of its multiyear investigation into companies’ drug pricing practices, already have Senate companions led by Sens. Debbie Stabenow (D-Mich.) and Tina Smith (D-Minn.).

[Politico](#) (4/7/2022): **MEDICARE’S CANCER PAYMENT PLAN DELAYED AGAIN** — The Centers for Medicare and Medicaid Services proposed delaying its controversial radiation oncology payment plan that was supposed to start last January, citing two previous delays that complicated implementation, according to a filing in the Federal Register on Wednesday.

[Modern Healthcare](#) (4/7/2022): **Biosimilars, generics to slow drug cost increases in 2022** - The FDA approved four biosimilars in 2021 and three came to market, curbing oncology drug costs.

[Axios](#) (4/7/2022): **Hospital drug spending up** - The COVID-19 treatment remdesivir accounted for more than 10% of what hospitals spent on drugs last year, and more than the next three drugs combined, according to a new report from the American Society of Health-System Pharmacists.

[Bloomberg](#) (4/7/2022): **Warnock Looks to Cap Drug Costs for Seniors:** Medicare recipients would get a \$2,000 annual cap on what they pay for drugs under a bill from a Senate Democrat facing one of the toughest reelection fights of 2022. In the measure, Sen. Raphael Warnock (D-Ga.) for the second time pulled a major drug pricing provision from his party’s stalled domestic spending package. Warnock also introduced a bill earlier this year to cap at \$35 per month what people with insurance pay for insulin. “Our country should never allow for our seniors to have to ration or skip the medication they need because they can’t afford it,” he said.

[Politico](#) (4/7/2022): **DEMS PEEL OFF MORE DRUG PRICING BILLS** — Democrats on the House Oversight Committee led by Chair Carolyn Maloney (D-N.Y.) are introducing three bills today aimed at lowering drug prices as the sweeping pharmaceutical reforms included in the Build Back Better legislation languish in the Senate, Alice reports.

[Bloomberg](#) (4/7/2022): **Cancer Research Head Sees Hope in Moonshot:** Clinical trial costs are rising, too many cancer research applications are going unfunded, and the White House proposed no new money for the National Cancer Institute despite its plan to cut the disease's death rate in half. Yet Ned Sharpless remains optimistic about the prospects for the institute he's led for nearly five years and its role in Biden's Cancer Moonshot 2.0 . "There will be significant investment in the NCI as part of the president's priorities in the future," Sharpless said in an interview. Read more from Jeannie Baumann.

[Bloomberg](#) (4/7/2022): **Biden Team Proposes to Delay Cancer Care Payment Model Again:** The Biden administration wants to postpone the start and performance period of a Medicare payment model for cancer care yet again. "We are proposing to delay the current start date of the Radiation Oncology Model to a date to be determined through future rulemaking, and to modify the definition of the model performance period to provide that the start and end dates of the model performance period for the RO Model will be established in future rulemaking," according to the proposal from the Center for Medicare & Medicaid Services. Tony Pugh has more.

[Politico](#) (4/7/2022): **FDA BEGINS STATE DRUG IMPORT TALKS** — The Food and Drug Administration has begun drug importation talks with five states, more than a year after Florida became the first state to finalize a rule that would let it import cheaper medicines from Canada.

[Politico](#) (4/6/2022): **DOCTORS, PATIENTS WANT TELEHEALTH TO CONTINUE ACROSS STATE BORDERS** — A Morning Consult poll on telehealth published today finds that health care providers and patients alike support telehealth practitioners being able to operate across state lines as the pandemic moves into a less critical phase.

[Bloomberg](#) (4/6/2022): **Drug Costs Part of Senator's Focus on FDA User Fees:** A greater number of cheaper, interchangeable versions of insulin and other costly brand-name biologics can help to significantly combat rising drug costs, senators argued at a hearing Tuesday. Members of the Senate Health, Education, Labor, and Pensions Committee questioned industry representatives at a discussion on the latest round of user fee agreements between the FDA and the prescription drug, generic, biosimilar, and medical device industries. User fees make up nearly half of the FDA's total funding.

[Politico](#) (4/5/2022): **SENATE TO SCRUTINIZE USER FEES AGREEMENTS** — The Senate HELP Committee is meeting at 10 a.m. EST today to discuss reauthorization of FDA's user fee programs with trade lobbies and The Pew Charitable Trusts.

[Politico](#) (4/5/2022): **FIRST IN RxP: BIPARTISAN BILL AIMS TO ONSHORE DRUG MANUFACTURING** — Sens. Tom Cotton (R-Ark.) and Tina Smith (D-Minn.) will introduce a bill Tuesday aiming to entice drugmakers to move their operations to the U.S., an issue that's likely to get more attention as Senate HELP leaders eye floor time for their pandemic preparedness measure, S. 3799. Worth noting: Smith sits on the HELP Committee.

[Axios](#) (4/4/2022): **The state of cancer** - Death rates for many individual cancer types, such as melanoma, have seen historic drops in the last decade, we reported as part of the Axios' Cancer Deep Dive over the weekend.



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