What is included in this newsletter:

- 2022 Midterm Election Special
- Up to Date List of Drug Pricing Legislation
- In The News

2022 Midterm Election Special

With the 2022 midterm election less than 30 days away, PRG would like to update SNO on where things stand and the likelihood that there will be a change of power in Congress. A change in power in Congress could greatly impact some of SNO’s priorities including appropriations, telehealth, and additional drug pricing reform. However, right here in River City, PRG suspects that Congress will reach a deal on FY23 appropriations before the 117th Congress concludes. This will most likely occur during the “lame duck” session before the 118th Congress starts in the new year.

Below please find a comprehensive update on where things stand, races in both the House of Representatives and Senate to watch, and who could gain control in the 118th Congress.

What a Difference–Year–Three Months Makes

- June 15, 2021 – Job Approval +10.2 (53.2/42.4); Gas @ $3.05
  - Biden riding high, having capitalized on his honeymoon period with the $1.9T American Rescue Plan, and turning to the rest of his Build Back Better agenda
- June 15, 2022 – Job Approval -15.7 (38.9/54.6); Gas @ $5.01
  - WH gripped by rising inflation, sagging growth while trying to resuscitate stalled agenda
  - USICA in “conference” limbo; reconciliation deal still very much in doubt
- Today – Job Approval -10.7 (42.8/53.5); Gas @ $3.72
  - String of legislative victories and improving economic indicators have boosted Biden ~6pts from a low ebb of 36.8% approval in late July; gas prices down 25% from June peak
  - Still historically unpopular, but on part with recent precedent thanks to Ds “coming home”
  - GOP struggles give Ds opportunity to mitigate House losses & even play offense in Senate
Three E’s of Midterm Elections

**Exposure**
- House: All 435 Seats
  - <60 ‘competitive’ races
  - 26 Presidential mismatches
  - Most Dem retirements since 1992
- Senate: ~1/3 of Chamber
  - Class 3= most purple
  - Battleground: Trump-Biden turf
    - Rs defending PA/VA, chasing GA/AZ
    - Don’t hold no Trump 2020 seats
- States: 46/50
  - 36 Gov races
  - 88 chambers: 6k+ seats (84%)
  - Trifectas at stake
    - 22 R, 13 D (11 Split)

**Environment**
- Presidential Approval
  - Historically low at ~43%
  - Significantly up from July nadir
- Generic Congressional Ballot
  - Ds wrest back narrow (~1pt) lead
  - Ballot share ~3pts ahead of Biden JA
  - Big pool of disapprovers still on fence
- Dobbs scrambles enthusiasm
  - Ds fired up, Rs on theirs heels
  - Synced precisely w/ decline in gas prices
- Green Wave
  - Rs risk getting swamped by Dem cash

**Events**
- Time=uncertainty/risk
  - A lot can happen in 6 weeks
- Economy
  - Continued fed hikes
  - CPI print
  - Q3 GDP release
- Natural disasters
- Gaffes/viral moments
  - ???

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**BRACEWELL**

State of Play: House of Representatives

The GOP needs 5 seats to retake House

**Post-WWII History favors a GOP takeover:**
- Party out of power averages gain of 26 seats
- Sub-50% POTUS sees party lose 37 on avg.
- Only 2 cycles where party in WH gained
- Impeachment-era Clinton; post811 W
- Rs begin with historically high baseline
  - Raw gains could be muted; just 57 competitive seats
  - Historic mean would yield record number of seats
- Redistricting puts 3 Dem seats squarely in GOP column
  - 212 “Lean R” or better; need just6 of 31 toaps

**Environment in flux**
- Biden approval remains historically poor at ~41.8%(%)"$
- Generic ballot roughly even (RCP 0.4, 538 +0.7)
- Mixed economic signals
  - Core inflation has stabilized; strong jobs numbers
  - 2nd straight qtr of negative growth; rate hikes looming

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**Cook Political Report Ratings of Competitive 2022 House Seats**

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<tr>
<th>Lean Democrat</th>
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<td>CA-09 Harder</td>
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<td>OH-01 Chabot</td>
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14 Dem, 3 GOP

22 Dem, 9 GOP

Source: Cook Political Report (9/21/2022)
Best House Barometer: Generic Ballot

- Generic ballot tracks closely w/ popular vote result
- Question currently close to even (RCP +0.4, 538 +1.4)
  - Reversion from early summer when Rs led by as much as 3
- Nature of map means Ds must win by ~2 for majority
- Party in power typically loses ground in home stretch
  - BUT past 2 months have shown marked Dem improvement
- Special elections point to rising Dem enthusiasm
  - Ds repeatedly outperforming Biden in low-turnout contests
  - Not always predictive: Ds won 7 of 9 in 2010 before losing 63 seats
- X Factor: How do the undecideds break?
  - Neither party above 45 in ballot share
  - Statistically likely to disapprove of Biden
    - BUT clear reflection of reservations with GOP
  - If they go to Ds, recipe for ’98/’02 style break with precedent

State of Play: US Senate

GOP defending majority of seats in echo of 2016
- 14 Democrats & 21 Republican
- Dems insulated from major losses
  - Big drop-off after NH

Consensus “Tossup” Seats
- NV: Mastro vs. Laxalt
- GA: Warnock vs. Walker

Dem Favored
- PA (OPEN): Oz vs. Fetterman (POLITICO, Inside Elections Toss -up)
- AZ: Kelly vs. Masters
- NH: Hassan vs. Bolduc

R Favored
- WI: Johnson vs. Barnes (Cook, 538, POLITICO Toss -up)
- NC (OPEN): Budd vs. Beasley
- OH (OPEN): Vance vs. Ryan

Sleeper races to watch
- CO, WA competitive on a good night for Rs
- FL competitive on a good night for Ds
- Wild Cards: AK, UT
Best Senate Barometer: Biden Approval

- With rapid alignment of senate outcome and partisan lean, Presidential approval is the single best measure
- Candidate quality, campaign cash, gaffes all matter at the margin; where they matter is a function of the political environment
- Outcome will correlate to Biden’s strength or weakness on election day
  - Good candidates can run single digits ahead of Presidential support
  - Very tough to consistently outperform job approval by double digits
- Notable disconnect between job approval ( -10.7) & generic ballot ( +0.4)
  - Net figure shows Dems outperforming Biden by 10 points
  - BUT Dem vote share is just 3 points higher than approval
- Undecided voters overwhelmingly disapprove of Biden
  - Opportunity for Rs “if” can be convinced to turn out
- Polling challenge: how to model this electorate
  - Both parties fired up in unprecedented ways
  - Recurring failures mean pollsters may be fighting the last war
  - Neither side truly trusts the numbers
  - “Likely voter” harder to screen than ever

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Key Senate Themes

- Rs enjoy significant advantage in political environment
  - Slightly better than November when they won VA and nearly picked off NJ
  - Biden has recovered from low ebb, but still mired in low 40s
- Dem advantages in terrain, recruitment, resources are real
  - Map limits Dem downside even in a bad cycle, and cash/candidate edge is keeping them competitive in contested purple state races
- Either way, Senate as an institution will see real change
  - Outgoing Rs Portman, Blunt, Burr, Toomey, Inhofe almost certainly give way to more bombastic successors
  - Much attention given to Trump’s primary struggles, but being pro-Trump is table stakes for GOP challengers. Open skeptics conspicuously declined to run

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2021: First election of the Biden era

Across the board shift to GOP from 2020
- VA GOV went from -10 to +2, full sweep of statewide offices
  - Margin moved toward Youngkin in 85% of precincts
- NJ GOV went from -13 to -3; close shave in "solid D" race
  - Senate President lost to a truck driver who spent $153

Not just marquee statewide races
- Rs flipped a state house seat in San Antonio Biden carried by 14
- Long Island goes red: Rs flip Nassau exec, Suffolk leg, both DAs
- GOP takes local races across CT, flipping leadership in 19 towns

Key Takeaways
- Biden was a drag on Ds (43% approval on election day)
- Trump-centric message failed to persuade Is, motivate Ds
- High turnout worked in Rs favor, especially in rural areas
- GOP continued to make gains among Hispanic voters

2022: Post-Dobbs Specials Galore

Dems overperforming in low-turnout elections
- String of near misses punctuated by big August wins
  - Held Trump/Biden swing seat in upstate NY
- Pick up Alaska seat in state Trump carried by 10
- Notable exception: R success in Hispanic CD

Looking Ahead: Divided Government

Two most plausible scenarios depending on size/scope of anticipated GOP victory

Scenario One: GOP House-Dem Senate

House
- Muted wave and statewide mismatches lend Rs oversight power but little else
  - Unusual conference enjoys little policy leverage beyond default brinkmanship
  - Discrete areas of bipartisan interest at committee level could bear fruit

Senate
- Dems maintain ability to control noms in exec branch and judiciary
  - Balance of power maintains possibility of bipartisan action
    - Easier to strike a deal that requires 10 Rs than one that needs 26+

White House
- Admin governs via regs/exec action with its preferred personnel

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Looking Ahead: Divided Government

Two most plausible scenarios depending on size/scope of anticipated GOP victory

**Scenario Two: GOP House & Senate**
- Partisan fundamentals eclipse other factors, GOP sweeps both chambers
  - Working House majority
  - 51 to 54 R Senate seats
- GOP can force significant legislative concessions
  - Spending levels, policy riders on must-pass bills
  - High ground for any bipartisan talks (e.g. energy, tax), BUT far fewer 60 vote opportunities
    - New chairs (e.g. Cruz @ Commerce, Paul @ HELP) unlikely to seek compromise
- Full veto power over noms, handcuffing admin regulatory agenda
- Oversight onslaught + Congressional Review Act (CRA) tools

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Looking Ahead: United Government(?)

Third option remains unlikely, but suddenly a conceivable outcome

**Scenario Three: Dem House & Senate**
- Dems buck history, ride Dobbs to preserve control of both chambers
  - Narrow House majority (again)
  - Likely to *pick up* Senate seats in this scenario
- 50-50 would reprise dynamics of 117th Congress
  - Dems control personnel/ noms and oversight
  - BBB Redux, within range of Sinemachin appetites
- 52+ Dems could open up a whole new universe
  - Wither the filibuster?
    - Roe codification, PRO Act, further climate action (CES/CEPP?)

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Looking Ahead: Fresh Faces

• Leadership Changes
  – GOP: relatively orderly transition
    • Speaker: McCarthy
    • Leader: Scalise
    • Whip: Emmer/Ferguson/Banks
    • Conference: Stefanik
  – Dems: elephant in the room
    • Pelosi expected to retire after election
      BUT loses clout, fundraising ability as lame duck
    • Until Pelosi makes intentions clear, jockeying happening behind the scenes
      – Top lieutenants 83 (Hoyer) & 82 (Clyburn)
      – CW favors Caucus Chair Jeffries (D – NY)

• Committee Shuffle
  – New members helming key committees
    • Members with seniority italicized
    • Contested races in bold

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Looking Ahead: Institutional Turnover/Polarization

• Regardless of the ultimate balance of power when the dust settles, makeup of parties in both chambers will emerge fundamentally changed
• Parties losing more than 1000yrs of seniority from beginning of 117th Congress
  – 592 years departing among House Dems alone
• Vacancies may end up costing a few seats at the margin, but overwhelmingly occurring in safe seats where the primary is tantamount to the general election
• Both parties trading leadership-friendly, policy-oriented members for more strident, partisan, populist newcomers
  – In some cases the retirements have been involuntary — Blue Dog Dems lost 2 key primaries to more progressive foes; centrist R David McKinley knocked off by Freedom Caucus colleague
• House and Senate will both be more polarized at the expense of the center

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Looking Ahead: What can get done?

- Congress has plucked much of the longstanding, low-hanging bipartisan fruit
  - Infrastructure; large scale COVID relief; China competitiveness
- Recent energy talks could inform the 60-vote market
  - Topics of conversation: border adjustment; regulations/permitting
- Other areas of potential bipartisan interest
  - Tech regulation/anti-trust
  - Privacy legislation
  - Higher education reauthorization
  - International tax (OECD)
- 2025 fiscal cliff looms large and only stands to grow
  - IRA syncs up ACA subsidies with TCJA individual title

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Tricky Votes Out of the Gate

- Debt Ceiling—likely to be reached in early 2023
  - Treasury could use extraordinary measures, perhaps through the summer months
    - Latest BPC estimate pegs Q3 X date
- Government Funding—possible in Q1
  - Potential omnibus through 9/30/23
  - Could serve as a forcing mechanism/vehicle to raise debt limit
- Midterm outcome looms large
  - Depending on margin of likely GOP House majority, leadership may have difficulty wrangling votes on either/both
  - Would-be GOP Whip Patrick McHenry bowed out citing the difficulty of that role

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GOP Oversight Agenda

• Internal—standard issue conservative critiques of federal agencies
  – Immigration—Title 42 rescission, border crisis
  – Education—CRT, COVID fallout
  – IRS—targeted leaks of federal taxpayer data

• External—populist bent to its focus, reflecting the mood of the base
  – “Woke capital”
    • Pressure on ESG industry, focus on fiduciary responsibility, proxy voting reforms, China hypocrisy
  – Big Tech
    • Censoring/deplatforming conservatives, data privacy, anti-trust/competition, Section 230, etc
  – Biden, Inc.
    • Hunter’s laptop, Burisma, CEFC, etc

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Biden Regulatory Agenda

• Legislative Implementation
  – IIJA
    • $110B sent to state/local govs as of July; $550 new spending in total
  – IRA
    • Podesta coming back to QB admin effort; launched CleanEnergy.gov
  – CHIPS.gov
    • NIST (Commerce) running point; strategy released last week

• Build Back Better themes by other means
  – Progressive Caucus pushing sprawling list of potential executive actions
    • Health care, immigration, labor, climate, housing, judicial reforms
      – Some legally dubious, but provides menu of options WH will be pressured on

• Continued climate/energy transition action
  – SEC climate rule (e.g.), greening the fleet, environmental justice

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2024: The Elephant in the Room

- The 2024 presidential calculus will inform everything that does and doesn’t happen in the next two years of Biden’s term
  - Rs will seek to deny the President any major “wins,” while conducting aggressive oversight meant to reinforce and compliment the eventual campaign messaging
  - Biden and Dems will look to previous examples of President’s bouncing back from midterm shellackings to win re-election, e.g. Reagan ’84, Clinton ’96, Obama ’12
- Talk quickly shifts to whether POTUS — and his predecessor — will run again
  - Both flawed candidates who nonetheless lord over otherwise unsettled parties, and who are each compelled in part by the anticipated candidacy of the other
- If not Biden, then who?
  - VP Harris has led every poll of a Biden-less field thanks to consolidation of AA support
  - Wide open race, but she would begin with clear advantages, especially in a divided field
- If not Trump, then who?
  - DeSantis has the most obvious opening, but open primary would turn into a free-for-all
  - Many would-be candidates limbering up and doing campaign-building spade work just in case

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

- **S. 4953 – Protect Drug Innovation Act**
  This bill, introduced on September 27, 2022, by Sen. Mike Lee (R-UT), would repeal prescription drug price control provisions of the Inflation Reduction Act.

- **S. 5002**
  This bill, introduced on September 29, 2022, by Sen. Rand Paul (R-KY), would allow for alternatives to animal testing for the purposes of drug and biological product applications.

- **H.R. 9011**
  This bill, introduced by Rep. Donald McEachin (D-VA), would amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a process to allow the holders of abbreviated new drug applications to make labeling changes to include new or updated safety-related information.

- **S.4918 – Increasing Prescription Drug Competition Act**
  This bill, introduced on September 22, 2022, by Sen. Maggie Hassan (D-NH), would amend the Federal Food, Drug, and Cosmetic Act to prohibit the use of patents, trade secrets, or other intellectual property to inhibit competition.

- **H.R. 8931 – Improving Access to Safe Medicines Act of 2022**
  This bill, introduced on September 21, 2022, by Rep. Buddy Carter (R-GA), would amend the Controlled Substances Act to require the Attorney General to remove a drug from scheduling within 180 days of a certain date pursuant to the recommendation of the Secretary of Health and Human Services.
- H.R. 8877 – Biologics Competition Act of 2022
  This bill, introduced on September 19, 2022, by Rep. Mariannette Miller-Meeks (R-IA), would direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs.

- H.R. 8857 – Generic Animal Drug Advancement Act
  This bill, introduced on September 15, 2022, by Rep. Nancy Mace (R-SC), would amend the Federal Food, Drug, and Cosmetic Act to make certain changes with respect to the approval of abbreviated applications for the approval of new animal drugs.

- H.R. 8828 – FDA Ethics Act of 2022
  This bill, introduced on September 14, 2022, by Rep. Ann Kuster (D-NH), would address potential conflicts of interest among entities serving as Food and Drug Administration contractors.

- H.R. 8641
  This bill, introduced on August 2, 2022, by Rep. Josh Gottheimer (D-NJ), works to mitigate the effects of the COVID–19 pandemic on incentives under the Federal Food, Drug, and Cosmetic Act for the development of orphan drugs, and for other purposes.

- S.4645
  This bill, introduced on August 3, 2022, by Sen. Gary Peters (D-MI), works to restrict the flow of illicit drugs into the United States, and for other purposes.

- H.R. 1274
  This bill, introduced on July 26, 2022, by Rep. Latta Robert (R-OH), amends the President to provide certain documents in the President’s possession to the House of Representatives relating to communications by or among any of the Department of Health and Human Services, the Office of National Drug Control Policy, the White House, the Drug Enforcement Administration, and the Department of Justice related to the executive branch’s recommendations for a long-term, consensus approach to reduce the supply and availability of illicitly manufactured fentanyl-related substances in the United States.

- H.R. 1284
  This bill, introduced on July 26, 2022, by Rep. Cathy McMorris Rodgers (R-WA), amends the Secretary of Health and Human Services to provide certain documentation to the House of Representatives relating to the negotiation of prices for prescription drugs under the Medicare prescription drug program.

- H.R. 8405
  This bill, introduced on July 18, 2022, by Rep. Cori Bush (D-MO), preserve access to abortion medications.

- H.R. 8299
This bill, introduced on July 7, 2022, by Rep. Gus Bilirakis (R-FL), amends the Federal Food, Drug, and Cosmetic Act to allow for devices with a predetermined change control plan to be marketed without submitting a supplemental application or premarket notification if the changes to such devices are consistent with such plan.

- **H.R. 8289**
This bill, introduced on July 5, 2022, by Rep. Abigail Spanberger (D-VA), requires the Secretary of Health and Human Services to promulgate a past due final rule with respect to direct-to-consumer prescription drug advertisements, and for other purposes.

- **H.R. 8270**
This bill, introduced on July 1, 2022, by Rep. Lucy McBath (D-GA), amends the Employee Retirement Income Security Act of 1974, title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide notices relating to prescription drug refills to individuals covered under such plans or coverage who reside in emergency areas during emergency periods.

- **S. 4446**
This bill, introduced on June 22, 2022, by Sen. Susan Collins (R-ME), modernizes the process of accelerated approval of a drug for a serious or life-threatening disease or condition.

- **H.R. 8078**
This bill, introduced on June 15, 2022, by Rep. Mark Green (R-TN), ensures that prior authorization medical decisions under Medicare are determined by physicians.

- **H.R. 7997**
This bill, introduced on June 9, 2022, by Resident Commissioner Jenniffer González-Colón (R-PR) amends 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.

- **S.4349**

- **S. 4338**
This bill, introduced on May 26, 2022, by Sen. Margaret Wood Hassan (D-NH), amends the Federal Food, Drug, and Cosmetic Act by providing for increased transparency in generic drug applications.

- **H.R.7208** — Price Relief, Innovation, and Competition for Essential Drugs Act
This bill, introduced on May 18, 2022 by Rep. Janice D. Schakowsky (D-IL), amends the Public Health Service Act to shorten the exclusivity period for brand name biological products from 12 to 5 years.
• **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 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 pharmacogenonomic 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**

- **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.

• **H.R. 2853**
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**

• **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 Re. 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.

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**In The News**

**STAT** (10/7/2022): **Drugmakers will be penalized if they hike prices on patients in private insurance market** - WASHINGTON — Democrats' drug pricing law will still penalize drugmakers if they hike prices on medicines for patients who have private insurance, a top Medicare official said Thursday.

**Axios** (10/7/2022): **Becerra leaves door open to march-in rights to lower drug prices** - Despite newly enacted drug pricing measures, the Biden administration hasn't ruled out more sweeping actions to lower the cost of medicines, including asserting control over the patents of treatments developed with the government's help, Axios' Peter Sullivan writes.

**Bloomberg** (10/7/2022): **Biden’s HHS Readies for Medicare Drug Negotiations, New Rebates** - Biden administration officials on Thursday downplayed criticisms and potential adverse effects of their sweeping Inflation Reduction Act (H.R. 5376), which—for the first time—will give Medicare the power to negotiate prescription drug prices for more than 65 million program beneficiaries. Early provisions of the IRA kicked in this week. Read more from Tony Pugh.

**Politico** (10/7/2022): **WHO’S THE NEXT ‘CURES’ CHAMPION OF THE GOP?** — After last month’s Energy and Commerce Committee dust-up over the future of CURES 2.0 — a second iteration of a 2016 biomedical research law — Lauren had a question for the legislation’s Republican
champion, Rep. Fred Upton of Michigan: Who in the party will take up the cause of promoting legislation on health care innovations once he retires later this year?

Politico (10/7/2022): ‘WE’VE GOT LOTS TO DO’ — That’s what HHS Secretary Xavier Becerra told reporters Thursday about the agency’s developing plan to implement the Inflation Reduction Act — which will, through Medicare, allow the government to negotiate prices for some drugs, cap the price of insulin and extend Affordable Care Act tax credits, Daniel reports.

Politico (10/7/2022): FDA ANNOUNCES FY23 USER FEE RATES — On Wednesday, the FDA announced user fee rates for fiscal 2023 for a variety of programs, including prescription drugs, biosimilars and medical devices. The agency also posted the FY23 fee rate for using a priority review voucher.

Bloomberg (10/6/2022): NIH Nominee Lag Complicates Confirmation - Biomedical research and the National Institutes of Health have so far checked off a lot of firsts for the Biden administration.

Axios (10/6/2022): Hospitals still aren't complying with price transparency rules - Almost two years after a Trump-era price transparency rule took effect, many hospitals are flouting a requirement that they post the prices for common goods and services online — with little risk of facing penalties, Axios' Victoria Knight writes.

STAT (10/6/2022): Medicare tasks a senior adviser with staffing its new drug pricing division - Medicare has tasked a senior adviser at the agency with assembling a small army of bureaucrats to get its new drug price negotiation program up and running.

Bloomberg (10/6/2022): Bill to Rein in Medicare’s Drug Coverage Restrictions: Reps. Nanette Barragan (D-Calif.) and Vern Buchanan (R-Fla.) unveiled a bill on Wednesday that would limit Medicare’s ability to restrict coverage of medicines, a move meant to ensure seniors have access to new medicines, Alex Ruoff reports. The bill was introduced in response to Medicare’s effort to limit coverage of the Alzheimer’s disease drug Aduhelm, which critics warned had limited efficacy but came with a high price tag.

Politico (10/6/2022): FIRST IN PULSE (I): ADVOCATES ASK BIDEN TO INTERVENE ON CANCER DRUG PRICE — Nearly 60 groups, including Public Citizen and Families USA, are asking the Biden administration to act to lower the price of a drug used to treat prostate cancer.

Axios (10/5/2022): Pharma can't give up on Dems as it tries to weaken drug price law - Pharmaceutical companies are trying to defang the new drug pricing law without declaring open war on the same congressional Democrats who crafted it and will continue to have powerful sway over the industry’s fortunes, Axios' Caitlin Owens and Peter Sullivan report.

Politico (10/4/2022): IRA’S BIOSIMILARS PROVISION GOES INTO EFFECT — The Biden administration began implementing one of the first pieces of the Inflation Reduction Act on Monday, temporarily increasing Medicare payments for certain biosimilars. The goal of the five-year bonus Part B payment is to “foster competition in the drug marketplace for conditions such as diabetes, cancer and immune disorders” while improving access, said CMS Administrator Chiquita Brooks-LaSure.
**Bloomberg** (10/4/2022): **Medicare Gives Biosimilars Boost, First Step in Drug Pricing Law**: Medicare will now pay more for lower-cost version of certain physician-administered drugs, the first step for the Biden administration implementing a new sweeping drug-pricing law (Public Law 117-169). The public health insurance program primarily for seniors will increase what it pays for biosimilars that cost less than their brand-name competitor in Medicare Part B for the next five years, starting Oct. 1. Read more from Alex Ruoff.

**Bloomberg** (10/4/2022): **Curbing Rising Drug Prices: Medicare Inflation Rebates Explained** - Makers of some of the highest-cost medications could start seeing Medicare rebate invoices as a provision of the Biden administration’s landmark drug pricing law takes effect.

**Politico** (9/30/2022): **SENATE PASSES REAUTHORIZATION OF FDA USER FEE PROGRAMS** — A short-term government funding bill — which includes a five-year reauthorization of the FDA’s user fee programs — sailed through the Senate on Thursday in a 72-25 vote.

**Bloomberg** (9/30/2022): **Pandemic, FDA Fixes on Lawmakers' Wishlist** - Lawmakers hope to attach a growing list of proposals—from overhauling the nation’s pandemic response to addressing mental health—to a year-end omnibus government spending bill.

**Politico** (9/30/2022): **STOPGAP BUDGET BILL PASSES SENATE** — The Senate approved a stopgap spending bill on Thursday that funds the government through mid-December, sending it to the House and likely averting a government shutdown that would hit in less than 48 hours, POLITICO’s Caitlin Emma and Marianne Levine report.

**Politico** (9/29/2022): **HOSPITALS PRAISE 340B RULING** — A federal judge ruled Wednesday that HHS must immediately cease reimbursement cuts for hospitals partaking in the 340B drug pricing program instead of waiting until 2023.

**Bloomberg** (9/29/2022): **Industry Readies Drug-Pricing Law Battle** - Drug Price Law to Spur Creative Claims as Industry Readies Fight: Medicare’s drug price negotiations are poised to turn into a legal battle as the government works out rules to implement them and critics eye ways to skirt limits on lawsuits. Kaustuv Basu explains.

**Politico** (9/28/2022): **BIDEN ANNOUNCES LOWER MEDICARE PREMIUMS** — Americans will be paying less for their Part B plan premiums next year — the first decrease in roughly a decade, President Joe Biden announced on Tuesday. The announcement comes six weeks before midterm elections, which will be crucial for Democrats.

**Bloomberg** (9/28/2022): **Biden Touts Medicare Cost Drop After Signature Bill**: President Joe Biden hailed premium cuts for elderly and disabled people on Medicare and slammed Republicans for opposing legislation that he says would also ease burdens on American families. At a White House event Tuesday, Biden said that the premium cut shows his administration is lowering costs for health services, even though last year’s payments were inflated due to costs associated with a new Alzheimer’s drug. Read more from John Tozzi and Jordan Fabian.

**Politico** (9/27/2022): **MCCONNELL WINS: RIDER-FREE UFA IN CONTINUING RESOLUTION** — Senate Minority Leader Mitch McConnell won his fight to attach a five-year reauthorization of the
FDA’s user fee programs without additional riders to a short-term government funding bill, three people familiar with the negotiations told POLITICO.

**Bloomberg** (9/27/2022): *Stopgap Bill Includes FDA User Fee Deal* - Key senators late Monday released language to reauthorize industry fees to the FDA with just days left for Congress to avoid a lapse in payments that fund roughly half of the agency’s budget.

**The Hill** (9/27/2022): *Health Care — Biden pushes drug price wins* - President Biden on Tuesday celebrated recent prescription drug reforms, proclaiming that Democrats had finally delivered an elusive win against Big Pharma.

**Axios** (9/27/2022): *A "clean" deal to fund the FDA* - A deal to renew funding for FDA drug and device evaluations will move forward this week, but without additional reforms to increase oversight of dietary supplements, lab-developed tests and other areas, Axios' Peter Sullivan writes.

**Axios** (9/27/2022): *Cancer screening risks not well documented* - Reporting on the physical and psychological harms from cancer screenings is inconsistent, making it hard to compare risks with rewards and potentially exposing patients to unnecessary hazards, Axios' Oriana Gonzalez writes off new research in the Annals of Internal Medicine.

**Politico** (9/26/2022): *TELEHEALTH, AT-HOME CARE GOLD RUSH* — Retail giants including Amazon, Best Buy, Walmart and CVS are trying to get a bigger piece of the health care market and investing billions to do so, but they might need the government to give them a hand to succeed, I report.

**Bloomberg** (9/26/2022): *GOP Touts Health-Care Plans if House Flips* - House Republican leaders, heading into November midterm elections that will determine control of Congress, have settled on a health agenda for next year: bipartisan, incremental changes to the system aimed at lowering costs.

**Politico** (9/26/2022): *THE GOP HEALTH CARE AGENDA* — About a month and a half from when they’re expected to win back the chamber, House Republicans rolled out their agenda Friday in Pennsylvania, POLITICO’s Sarah Ferris and Olivia Beavers report.

**Axios** (9/26/2022): *A new surprise billing court challenge* - Providers are once again challenging the Biden administration on the surprise billing law and the method for deciding who picks up the tab in disputes over out-of-network care.

**Politico** (9/23/2022): *WHITHER CURES 2.0?* — On Wednesday, during what was likely the House Energy and Commerce Committee’s last markup of the year, Rep. Diana DeGette (D-Colo.) gave an unexpected update: DeGette and retiring Rep. Fred Upton’s (R-Mich.) CURES 2.0 legislation was supposed to be on the docket this month, but majority staff pulled the bill from markup after Republicans threatened to offer “poison pill amendments.”

**Axios** (9/23/2022): *Drug pricing law a GOP target* - Some key House Republicans are calling for the repeal of Democrats’ newly-passed drug pricing measure if the GOP flips control of one or both chambers of Congress next year, Axios' Peter Sullivan and Victoria Knight write.
Bloomberg (9/23/2022): Senate Nears FDA Deal to Ride on Stopgap - The Senate is close to finalizing a bipartisan deal reauthorizing FDA user fees with just days left until the existing agreement expires.

Politico (9/23/2022): RAND PAUL WEIGHING POTENTIAL COMMITTEE GAVELS — Sen. Rand Paul (R-Ky.) told POLITICO he will decide after the election whether he will push for the top Republican slot on the Senate Homeland Security and Governmental Affairs Committee or the Senate HELP Committee.

Axios (9/23/2022): Deal reached to renew FDA user fees - Senate and House health committee leaders on Thursday reached an agreement to renew programs that fund key Food and Drug Administration programs for another five years, Victoria and Peter report.

Politico (9/23/2022): FIVE MORE YEARS — The leaders of the Senate HELP Committee and the House Energy and Commerce Committee reached a deal on Thursday to include a five-year reauthorization of the FDA’s user fee programs and a few smaller policy riders on a short-term government funding bill this month, David reports. The agreement does not include overhauls of how the FDA regulates diagnostics, dietary supplements and cosmetics.

Washington Post (9/22/2022): Biotech Aims to Detect Cancer Early. But Tests Have a Long Way to Go. - Biotechnology is full of tantalizing promises, but few as appealing as this: a test that can screen for any kind of cancer early, allowing patients to start treatment early and have a better chance at surviving.

Bloomberg (9/22/2022): Democrats Slam ‘Poison Pills’ on Cures 2.0 - Partisan bickering is holding up a biomedical innovation bill in the House, the legislation’s main Democratic sponsor said.

Politico (9/22/2022): BIPARTISAN DRUG PRICING BILL — Sens. Maggie Hassan (D-N.H.) and Mike Braun (R-Ind.) plan to introduce a bill today aimed at lowering prescription drug costs.

Axios (9/22/2022): Cancer deaths fall with treatments, screening - The decline in cancer deaths has accelerated in recent years, reaching a 2.3% annual drop every year between 2016 and 2019, according to the latest American Association for Cancer Research Cancer Progress report.

Politico (9/21/2022): PROVIDERS DROP SURPRISE BILLING SUIT — But another is likely on the way. Provider groups, including the American Medical Association and the American Hospital Association, seek to drop their lawsuit against the federal government over how disputes in surprise bills are arbitrated.

Bloomberg (9/21/2022): Califf Hopeful for FDA Deal as Lapse Looms - Appropriations talks at the Capitol are in full swing this week as time is running out for lawmakers to reauthorize the Food and Drug Administration’s user fees. But the agency’s commissioner, Robert Califf, is expressing optimism.

Politico (9/21/2022): GOP EYES TELEMEDICINE EXPANSION — Rep. Kevin McCarthy is set to roll out Republicans’ “Commitment to America” agenda Friday, a spokesperson for the House minority leader told Future Pulse.
Axios (9/21/2022): **Biosimilars aren't always that much cheaper** - The prices of biosimilars — the generic equivalent of drugs known as biologics, which are made from living organisms — are often not much lower than their brand-name originator products when purchased through employer-sponsored insurance plans, according to a new report from the Health Care Cost Institute.

Politico (9/20/2022): **SURPRISE! USER FEES TALKS CONTINUE** — Negotiations between the leaders of the Senate HELP Committee and the House Energy and Commerce Committee on a package to reauthorize the FDA’s user fee programs for drugs and medical devices continued over the weekend, but no resolution was reached. Negotiations are centered on approximately 15 to 20 riders to the base reauthorization, according to five industry lobbyists and congressional aides granted anonymity to discuss the ongoing talks.

Politico (9/19/2022): **AND MEDICARE PATIENTS EMBRACE TELEHEALTH** — A new study published in JAMA Health Forum found Medicare patients took advantage of pandemic-era policies permitting them to see doctors who practice in other states via phone or video call, POLITICO’s Ben Leonard reports.

Bloomberg (9/19/2022): **Advocates Target Pharmaceutical Middlemen** - Drug pricing advocates fresh off a major win say they’re turning their attention to changes for pharmaceutical industry middlemen and to curbing high launch prices for new medicines.

Bloomberg (9/19/2022): **Skyrocketing Prices Fuel Drive for Fresh Crackdown on Drug Costs** - Drug pricing advocates fresh off a major win say they’re turning their attention to changes for pharmaceutical industry middlemen and to curbing high launch prices for new medicines.