



Cozen Currents: The Inseparable Line Between Governing and Campaigning

The Cozen Lens

- Members of Congress have returned to Washington with a lengthy to-do list. Most pressing is appropriations given the potential for a government shutdown at the end of this month. Lawmakers will address this issue and others in the shadow of the upcoming 2024 elections.
- President Biden's regulatory agenda is picking up speed and so are the legal challenges. However, court defeats and political victories are not necessarily mutually exclusive.
- Now that the Biden administration has released its list of 10 drugs that it plans to target for Medicare negotiations, the pharmaceutical industry is ramping up its counterattack.

Congress' To Do List for Rest of 2023

House Republicans. The House Freedom Caucus (HFC) is expected to exert disproportionate influence over House leadership this fall.

- House Speaker Kevin McCarthy (R-CA) has taken the opposite approach of his predecessor, Rep. Nancy Pelosi (D-CA), who consistently shielded her frontliners from tough votes. By contrast, McCarthy, from whom conservative hardliners regularly threaten to revoke the speaker's gavel, has consistently put his most vulnerable members, 18 of whom hail from districts won by President Biden in 2020, in difficult positions. For example, he backed the HFC's demand for FY24 funding cuts and included hardliners' "culture war" amendments in the House's version of the National Defense Authorization Act (NDAA). McCarthy recently said privately that he plans to launch an impeachment inquiry of Biden by the end of September over his son Hunter's business dealings. Forcing moderates to take tough votes on funding cuts, social issues, and impeachment keeps the HFC satisfied but could put the House GOP majority at risk in 2024.
- The HFC announced last month that its support of a continuing resolution (CR) to avert a government shutdown at the end of this month would be conditioned on inclusion of contentious policy riders. These have to do with the border, elimination of so-called "woke" Defense Department policies, and withholding funding for the Department of Justice's investigations into former President Trump, which they term "weaponization" of the federal government but could be politically toxic for moderates.
- HFC members may see a shutdown as a plus in their bid for funding cuts. Rep. Bob Good (R-VA) said in a July news conference that "we should not fear a government shutdown" and if the government closed, "most of the American people won't even miss it." While a shutdown may not be desirable, it's a small price to pay for McCarthy to shore up support with his right flank. By the time the 2024 elections roll around, an October 2023 shutdown will not be top of mind for voters.



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Senate Republicans. Senate GOP leadership has sought to distance itself from House counterparts in FY24 appropriations.

- While House Republicans have written their spending bills below the levels in the debt ceiling agreement earlier this year, the Senate process has been more bipartisan, with members of both parties supporting the spending caps from the deal plus \$13.7 billion in emergency funding.
- In his recent news conference that got overshadowed by a medical incident, Senate Minority Leader Mitch McConnell (R-KY) described the spending situation as "a pretty big mess" and said that the House's funding levels are "not going to be replicated in the Senate." In remarks last week, McConnell urged passage of Biden's \$40 billion supplemental funding request for Ukraine aid and disaster relief. Mainstream conservatives and MAGA Republicans are divided on the Ukraine aid, and it was reported last week that McCarthy is considering advancing a CR with only the disaster relief, using the Ukraine funding to bargain for stronger border security measures.
- While McCarthy's job depends on staying in conservative hardliners' good graces, McConnell does not face a similar threat. The Senate GOP faces a highly favorable map in 2024, when Democrats will be defending 10 seats in competitive races, including three in states won by Trump in 2020. After failing to win the majority due to poor candidate quality in 2022, Republican Senate leadership will want to preserve their advantage in next year's elections. Avoiding the House GOP's drama and taking a bipartisan approach to appropriations is helpful in this regard.

Senate Democrats. In comparison with the House GOP, Senate leadership is portraying the upper chamber as the adults in the room.

- In floor remarks last week, Senate Majority Leader Chuck Schumer (D-NY) stated that preventing a shutdown is a top priority for the Senate and called on the House GOP to embrace bipartisanship. Today, the Senate will begin considering a "minibus" package including the military construction/veterans' affairs, agriculture, and transportation/Housing and Urban Development spending bills. Passing its own bills at higher levels while the House is in disarray tees up the Senate to take a stronger hand in funding negotiations with the lower chamber.
- Schumer is seeking to exploit the split between House and Senate Republicans. In his "Dear Colleague" letter to Senate Democrats earlier this month, Schumer drew sharp distinctions between the House and Senate GOP. This strategy reinforces the "extremist MAGA Republicans" attack line that Biden has deployed for his re-election. The president has largely avoided attacking Trump directly, instead adopting a broader, less personalized target of GOP extremism.
- Appropriations is likely to dominate the fall due to the potential for a government shutdown, but Congress has a lengthy to-do list for the remainder of 2023, which includes the NDAA, Farm Bill, the national flood insurance program, Federal Aviation Administration reauthorization, and several expiring public health and workforce programs and addressing scheduled Medicaid DSH cuts. These will all likely take a backseat to government funding for the immediate future though.

How to Define Victory on the Regulatory Front

The Many Meanings of Victory. The regulatory process is rarely straightforward, but the increasing challenges of President Biden's progressive agenda in the courts have meant that what constitutes victory is not the same on every issue.

- In theory, victory for a regulator should be as simple as promulgating a new rule, having it come into effect, and then pursuing enforcement actions against violators. Legal challenges may cause the agency to return to the drawing board, but these should not be too common if the rules are crafted within the agency's established legislated authority.
- Biden's embrace of a progressive agenda has freed regulators to push the boundaries of their jurisdiction and try non-traditional regulatory approaches. Meanwhile though, the conservative-dominated Supreme Court has been increasing its scrutiny of regulatory actions.
 This has resulted in more court cases, often forcing agencies to become more circumspect

while crafting rules. It also means that victory is less often defined traditionally and sometimes even legal losses are considered as just one battle in a broader war. For example, Federal Trade Commission (FTC) Chair Lina Khan celebrated having the FTC's novel legal interpretation validated despite losing its high-profile case seeking to block Meta's acquisition of Within.

Interpretation is Everything. When regulators have pushed the limits of their authority under the Biden administration, they have often run into legal threats or challenges, but they can sometimes still secure wins with these ambitious approaches.

- Securities and Exchange Commission (SEC) Chair Gary Gensler's approach to crypto has been regulation by enforcement rather than writing rules for the industry. Under this strategy, Gensler has taken an expansive view of what constitutes a security and thus falls under his agency's purview. The result has been some significant legal battles, including high-profile defeats, but a review of Gensler's record suggests that the SEC has largely succeeded on net.
- Khan is one of the most progressive and aggressive regulators in the Biden administration. The agency under her watch has pursued rulemakings on topics ranging from data privacy to non-compete clauses, all under an expansive interpretation of the FTC's authority. Many of her most controversial rules have yet to be finalized and are expected to face legal challenges, but even if overturned, Khan would likely see such setbacks as just one avenue for regulating the particular activity being ruled out.

Messaging Matters. Biden has accepted the risk of this progressive agenda and broad interpretation of agency authority partly because he is looking for political victories even if they aren't always accompanied by substantive policy wins.

- Just like messaging bills in Congress, Biden sees a value in at least pursuing these
 regulatory efforts as a chance to demonstrate to the Democratic base that his
 administration is taking action on these issues. Even if not consistently successful,
 showing the effort yields political benefits.
- This dynamic emerged after the Supreme Court overturned Biden's first attempt at student loan relief. Advocates, while disappointed, were looking to the White House for how it would respond and whether it would continue pursuing a policy they prioritized. When Biden announced his next attempt at forgiveness shortly thereafter, this was welcomed as a sign that the Biden administration is not giving up on the issue even if this backup plan has even less chance of being successful in surviving judicial review.

The Coming Battles in the Prescription Drug Price War

Order of Battle. The Inflation Reduction Act (IRA) has a prescribed sequence of events on the road to Medicare negotiating prescription drug prices from the initial list all the way through to the "maximum fair price" being set for calendar year 2026.

- On August 29th, the Centers for Medicare and Medicaid Services (CMS) released its initial 10 drugs. The next step is that each of the relevant companies must sign up to the negotiation program by October 1st or be subject to excise taxes between 65 percent and 95 percent. Then CMS and each manufacturer will engage in negotiations until August 1st, 2024, and then the maximum fair price for each drug is publicly announced on September 1st, 2024, with prices taking effect January 1st, 2026.
- This process builds cumulatively, so CMS will select additional drugs in 2024 for 2027. In 2028, the agency can also expand its selection to Medicare Part B products, which covers prescription drugs administered in doctors' offices, hospitals, and infusion centers.

Pharma Launches Its Counterattack. Drug manufacturers have chosen to sue CMS and claim that key parts of the IRA are unconstitutional as they want to delay implementation of the law and eventually overturn parts of it to reduce its impact on their revenue.

• There are currently eight lawsuits against CMS to block implementation of the IRA, six from manufacturers and two from trade groups. Since the announcement of the specific drugs being initially targeted, one lawsuit was withdrawn because the company's product

was not included.

- The cases have been filed all over the country in the hope that there are competing judicial opinions that advance the manufacturers' arguments all the way to the Supreme Court.
- The timeframe between now and the October 1st deadline for the relevant companies to sign on to the negotiation process is critical to see if any of the pending suits result in a federal district court imposing a temporary injunction on the negotiation process. The first big hearing is this Friday for the US Chamber of Commerce case filed in Ohio. There may also be more suits filed from the four firms whose drugs were included by CMS but which have yet to initiate litigation.

The Next Battlefield. Senate Majority Leader Chuck Schumer's (D-NY) September 1st "Dear Colleague" letter stated that he intended to advance legislation to bring down the cost of insulin in the commercial insurance market as well.

- Eli Lilly, Sanofi, and Novo Nordisk pledged in March 2023 that they would reduce the price of certain insulins they produce by as much as 78 percent starting in 2024.
- Democrats want to codify these promised reductions and ensure they apply to all insulins, not just those selected by the companies and that the out-of-pocket cap matches the IRA's \$35 out-of-pocket per month cap for Medicare.
- Although some Republicans, particularly in the Senate, support these efforts, garnering support in the House amongst Republicans will be an uphill battle.