

OSMA 2024 Fall Meeting Update from Capitol Hill

Clayton Hall, MDMA's EVP Government Affairs
October 23, 2024



ABOUT MDMA

Founded in 1992 by a few CEOs of small MedTech companies who desired a distinct voice in DC

- We provide advocacy, educational services and assistance

Today we represent hundreds of member companies

- Small innovators to largest device, diagnostic and digital services companies in the world
- We maintain our founding mission, principles and distinct voice for innovators, entrepreneurs and patients

MDMA's Mission: Promote patient access to safe and effective medical technologies that improve health outcomes

- Responsive to the needs of our members
- Focus is a key to our success

Website: <https://www.medicaldevices.org>

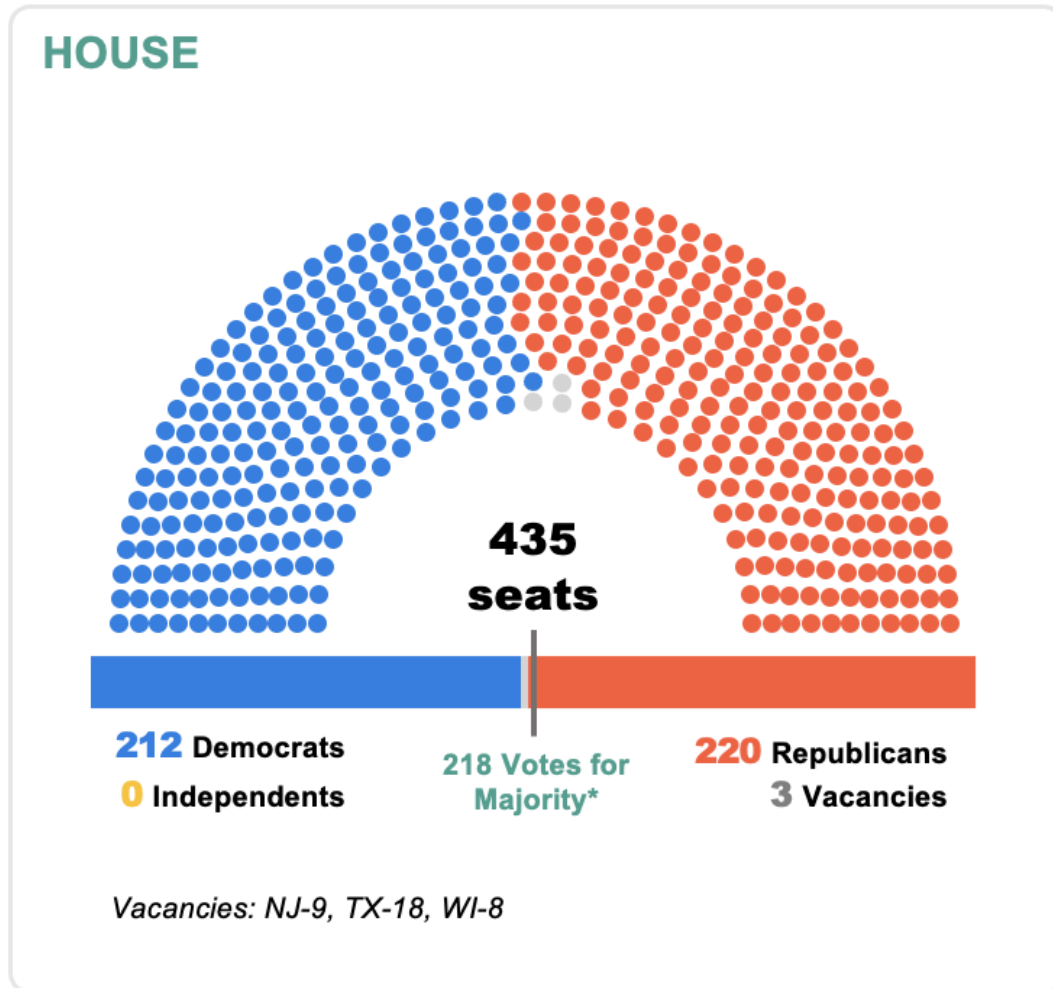
AGENDA:

- 1. CONGRESSIONAL LANDSCAPE & LEGISLATIVE OUTLOOK**
- 2. 2024 ELECTIONS**
- 3. FDA**
- 4. AI/ML**
- 5. EMERGING CHEMICALS**



CONGRESSIONAL LANDSCAPE & LEGISLATIVE OUTLOOK

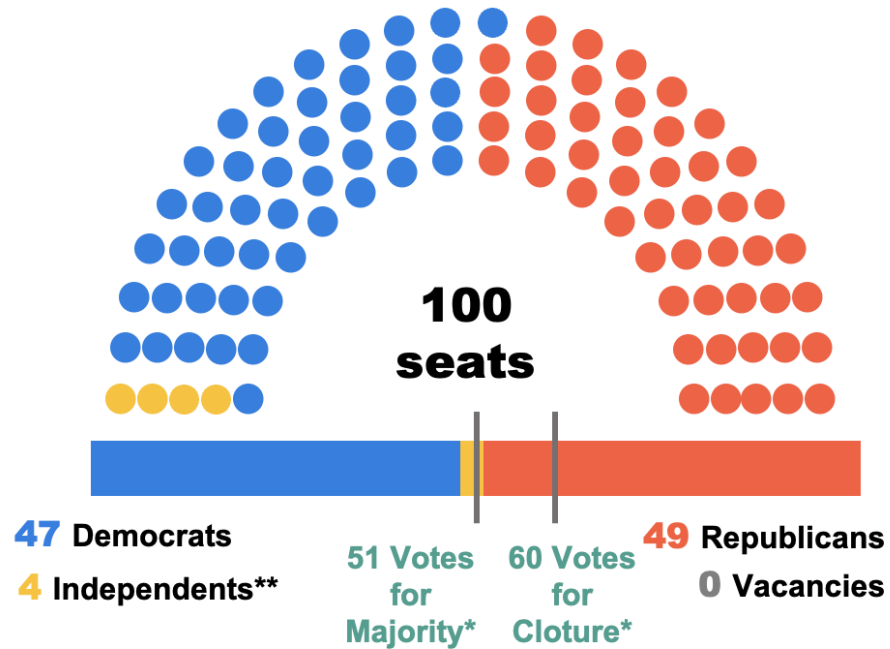
HOUSE BALANCE of POWER



- **Speaker Johnson's high-wire act to keep Speakership** - balancing demands from the far right and former President Trump against the reality of striking a consensus with GOP moderates and Democrats to pass legislation.
- **Johnson has canceled votes** on key GOP priorities multiple times this year because they wouldn't pass.
- Most recently, he was forced to abandon his plan to avoid a government shutdown by pairing a six-month funding extension with a bill requiring photo ID to register to vote.

SENATE BALANCE of POWER

SENATE

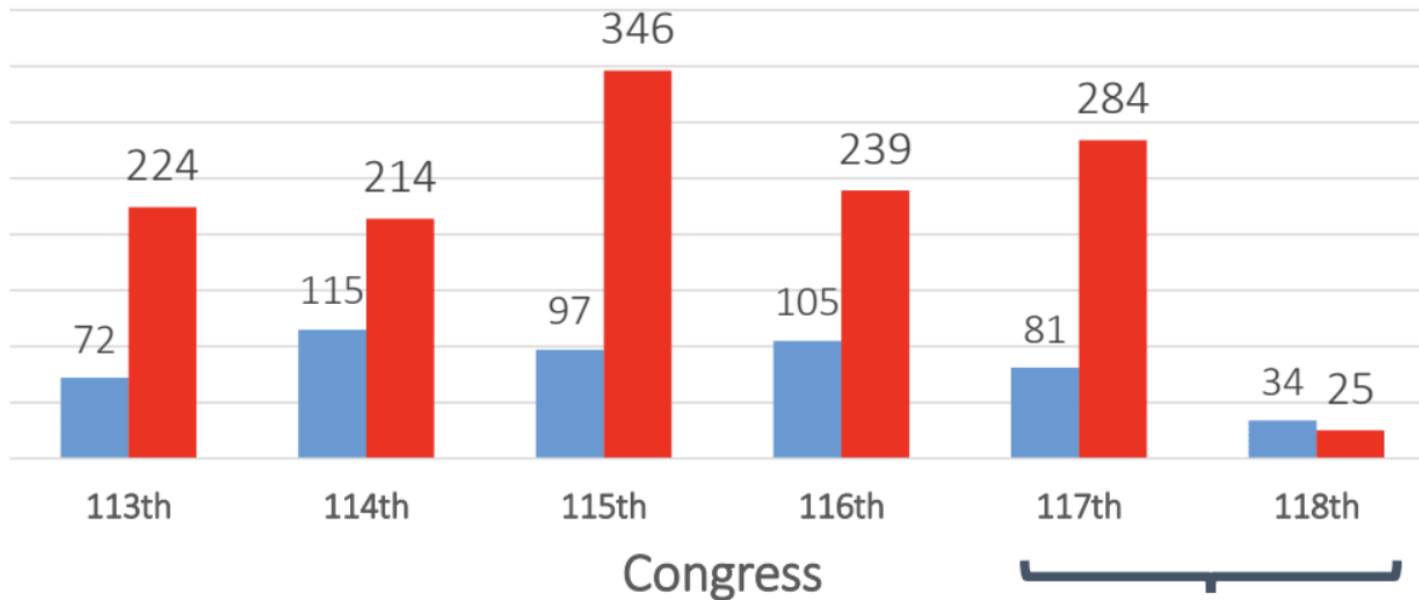


- Even with a narrow 51-seat Dem majority, the **Senate continues to dictate the terms of must-pass legislation** like government funding.
- **60 votes** are needed to overcome the filibuster and pass most bills, but moderates are willing to cross the aisle to avoid a shutdown.
- **Big changes ahead in 2025:** 1) new GOP Leadership with Sen McConnell stepping down and 2) Dems likely to end the filibuster if they keep the majority

HISTORICALLY UNPRODUCTIVE CONGRESS

Enacted Legislation Over Last Six Congresses

- Enacted Legislation In First Congressional Year
- Enacted Legislation After First Congressional Year



- Overly simplistic to judge Congress on the number of bills signed into law, but the decline is sharp and notable.
- **84% decrease from 117th to 118th Congress.**
- **Driving factors include:**
 - **Divided government**, deep polarization in the electorate
 - Extremely **narrow majorities** in Congress
 - House GOP plagued with **intraparty fights**
- **New normal? Prelude to 119th Congress?**



THE ART OF THE POSSIBLE: The outcome of the elections will impact each party’s willingness to negotiate on a larger or smaller “end of year” legislative package. A party that sweeps the White House and Congress may prefer to only address the “must pass” items and delay others until 2025 when they have a stronger hand.



GOVERNMENT FUNDING: Congress will have to pass another government funding bill to avoid a shutdown in December; the election results will determine whether it’s a larger “full year” bill that can carry other policies vs a smaller short-term punt into early 2025 with fewer riders.



HEALTH CARE: Must-pass policies include expiring Medicare policies, the Support Act (opioid addiction services), telehealth, and looming cuts to physician payments. A larger package could consist of policies on price transparency, site-neutral payment, Pharmacy Benefit Managers (PBMs) reform, drug shortages, and priorities like HR 1691 (Medicare coverage for breakthroughs) and BIOSECURE Act

- **BIOSECURE Act—prohibits US government (USG) contracting, loans, and grants with “biotechnology company(ies) of concern (CoC)” —specifically BGI, MGI, Complete Genomics, and WuXi Apptec in China AND any entity who uses their services in support of a USG contract, including medtech**
 - Impacts direct contracts with USG, including with DoD, VA, NIH, Bureau of Indian Affairs, and the Strategic National Stockpile; not Medicare or Medicaid reimbursement
 - Grandfather's existing contracts, from the date of enactment through 2032, prohibit new ones
- **Passed the House by 306-81 vote this month and is a candidate to be included in an end-of-year package**
- **Impacted companies should inventory their contractual relationships with CoCs, and business exposure in China more broadly, as Congress looks to pass BIOSECURE and additional policies targeting China**



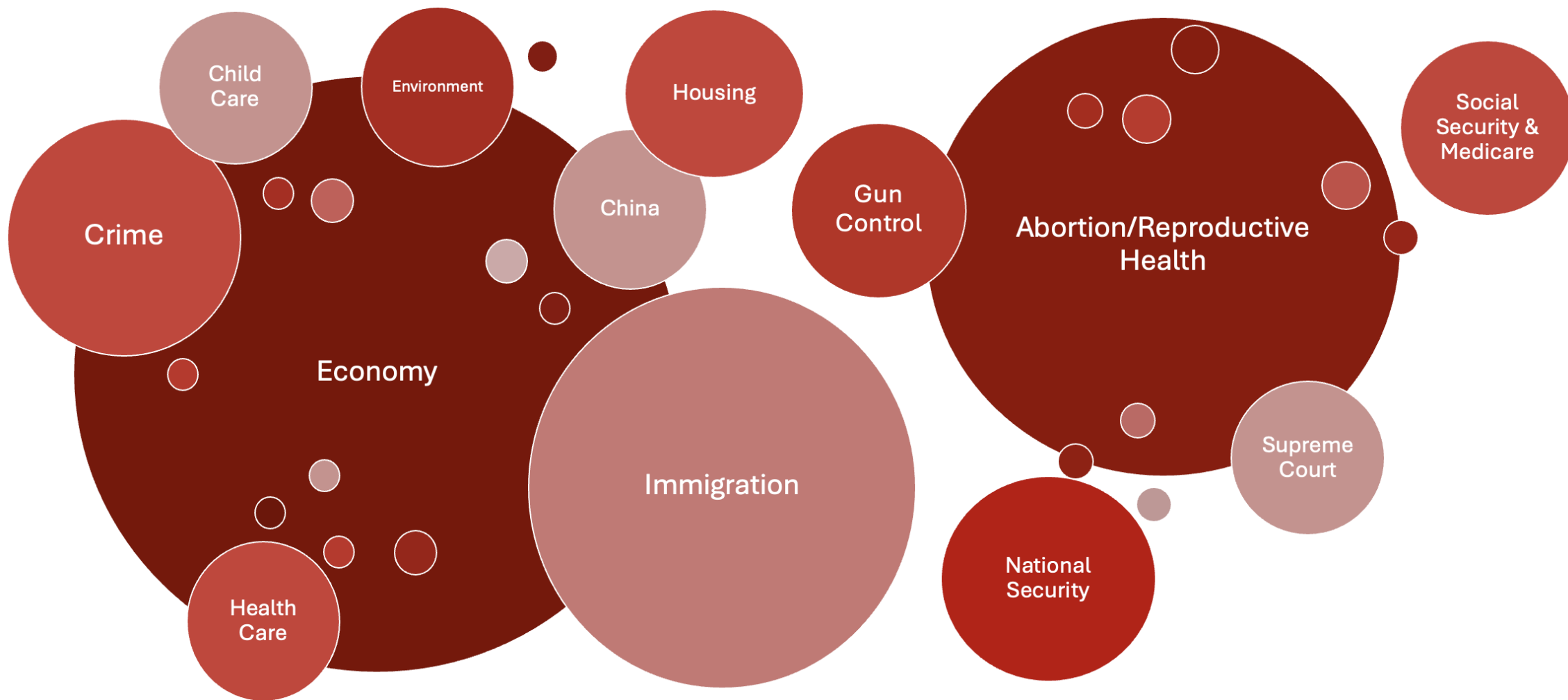
HR 1691 – Medicare Coverage for Breakthroughs

- **H.R. 1691, Ensuring Patient Access to Breakthrough Medical Products Act, would provide four years of automatic Medicare coverage for FDA-approved Breakthrough devices.**
- **Major progress this Congress with the House Ways & Means Committee passing a new version of the bill by a bipartisan 36-5 margin in late June, after the House Energy & Commerce Committee's Health Subcommittee's 21-6 bipartisan vote last November.**
- **The Ways & Means passed bill preserves the bill's core and lowered the Congressional Budget Office's (CBO) cost of the bill to \$1B (from previous estimates of \$10B+) over ten years.**
 - Energy & Commerce chose not to advance the bill even at a lower price tag, citing disagreements over revenue raisers to "offset" its cost.
- **Senate companion legislation to be introduced in November.**
- **Success this year will depend on whether a large healthcare package develops at the end of the year, and if GOP believes Trump will address by regulation should he win a second term.**

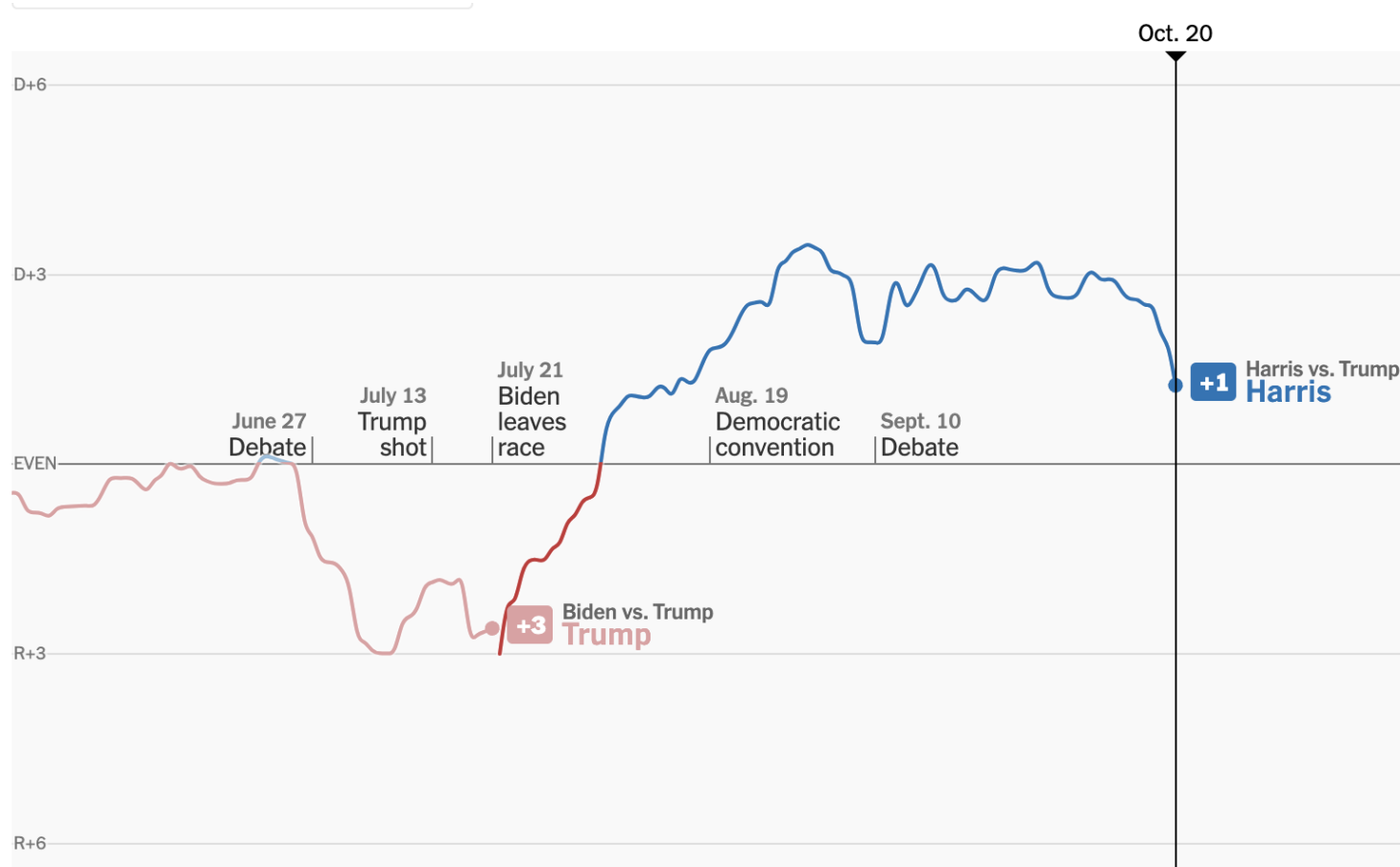


2024 ELECTIONS

THE ISSUES THAT MATTER



PRESIDENTIAL RACE OVERVIEW

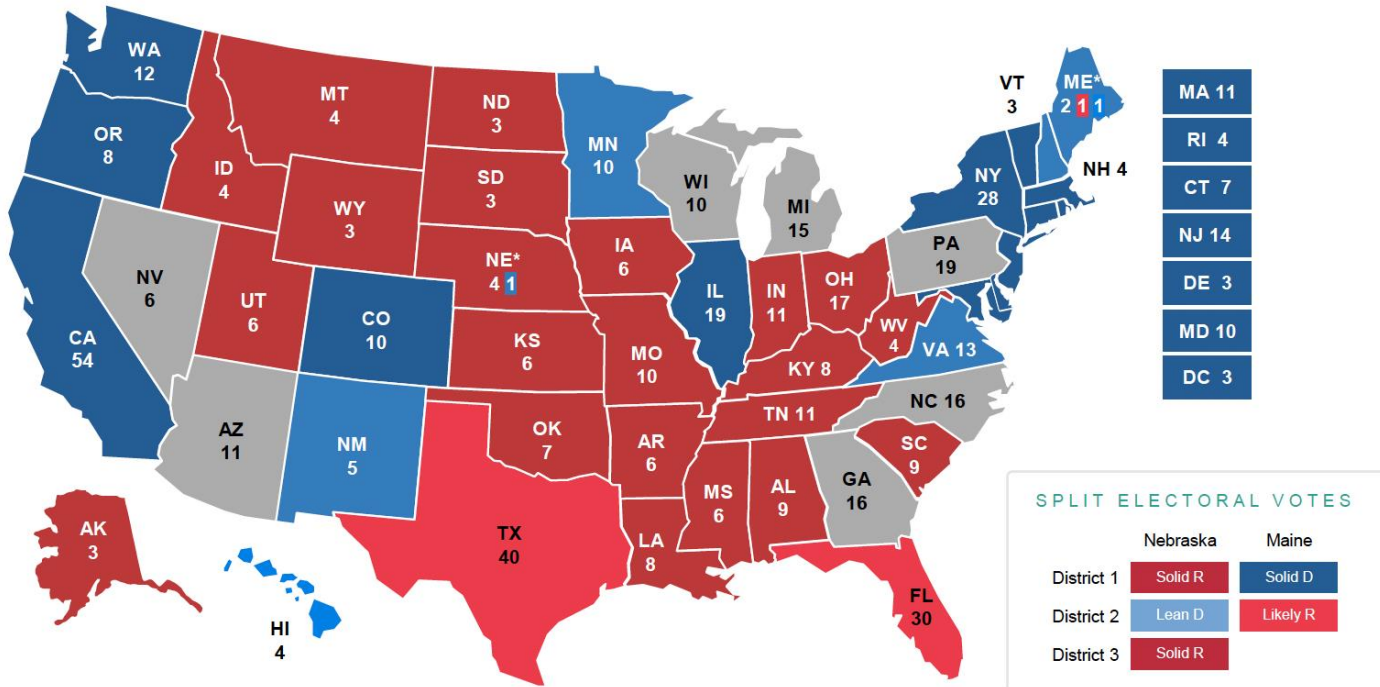


- The Presidential race was tight before the June 27th debate between President Biden and Trump.
- After the debate and the assassination attempt, the national polling average widened to Trump +3 before Biden announced he would leave the race.
- As Harris has consolidated support among Democrats, national polls have shown her gaining ground but have softened more recently
- **National polling can be misleading. The race is essentially tied – or within the polling margin of error – in the seven swing states that will decide the election**

THE PATH TO 270

Cook Political Report: 2024 Electoral College Ratings

■ Solid D ■ Likely D ■ Lean D ■ Toss Up ■ Lean R ■ Likely R ■ Solid R



- 93 Electoral Votes up for grabs; **Harris leads Trump 226-219 in uncontested states.**
- **Most expect the race to go the way of PA;** without it, the path to victory would be very narrow for both candidates.
- **Case for a Harris** = Galvanized critical blocs of the Democratic base who had lost interest in Biden. Her campaign has a major fundraising advantage and robust infrastructure in the battleground states.
- **Harris Closing Argument** = Remind swing state voters why they rejected Trump in 2020 - dangerous and unfit. Grow the gender gap with women, steal Haley Republicans, and recapture black and Latino male votes.
- **Case for Trump** = Favored on the key issues – economy, inflation and border security. He could be viewed as the change candidate versus a deeply unpopular Biden Administration.
- **Trump Closing Argument** = Voters can choose four more years of the Biden Administration or the return to the prosperity of the first Trump term. Targeting "low propensity" & new voters – young males.

SWING STATE POLLING

With less than **13 days** to the election, all eyes will be on these states: PA, WI, MI, GA, AZ, NC, and NV. Just a few thousand votes in each will likely determine the winner.



Pennsylvania	48.2%	48.2%	TIED
Wisconsin	48.5%	48.2%	Harris +0.3
Michigan	48.2%	47.7%	Harris +0.5
Arizona	47.5%	49.2%	Trump +1.7
Georgia	47.6%	49.2%	Trump +1.6
Nevada	48.2%	47.6%	Harris +0.6
North Carolina	47.9%	48.7%	Trump +0.8

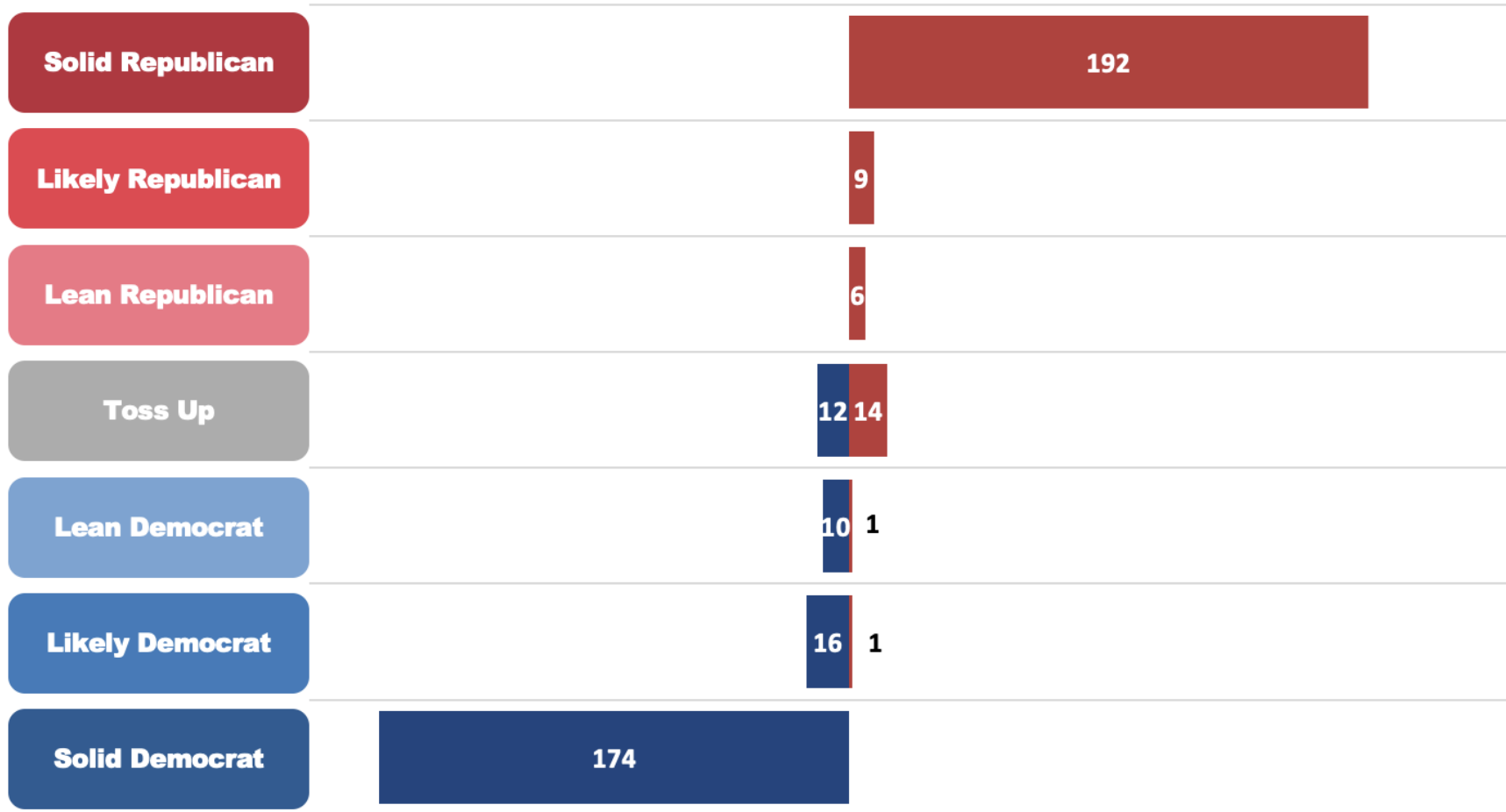
2024 SENATE MAP FAVORS GOP

Solid D	Likely D	Lean D	Toss Up	Lean R	Likely R	Solid R
CA-OPEN CT-Murphy DE-OPEN HI-Hirono MA-Warren ME-King (I) MN-Klobuchar NJ-VACANT NM-Heinrich NY-Gillibrand RI-Whitehouse VA-Kaine VT-Sanders (I) WA-Cantwell	MD-OPEN	AZ-OPEN (I) NV-Rosen	MI-OPEN OH-Brown PA-Casey Jr. WI-Baldwin	MT-Tester NE-Fischer TX-Cruz	FL-Scott	IN-OPEN MO-Hawley MS-Wicker ND-Cramer NE-Ricketts TN-Blackburn UT-OPEN WV-OPEN (I) WY-Barrasso

- There are 34 Senate seats up for reelection this cycle. GOP entirely on offense with no “toss up” seats to protect.
- GOP can take control with a net gain of two seats or by winning the Presidential election and a net gain of one seat.
- WV will flip to GOP, MT next most likely, with many believing the floor for GOP is 51 seats heading into November.



2024 HOUSE ELECTIONS TOO CLOSE TO CALL

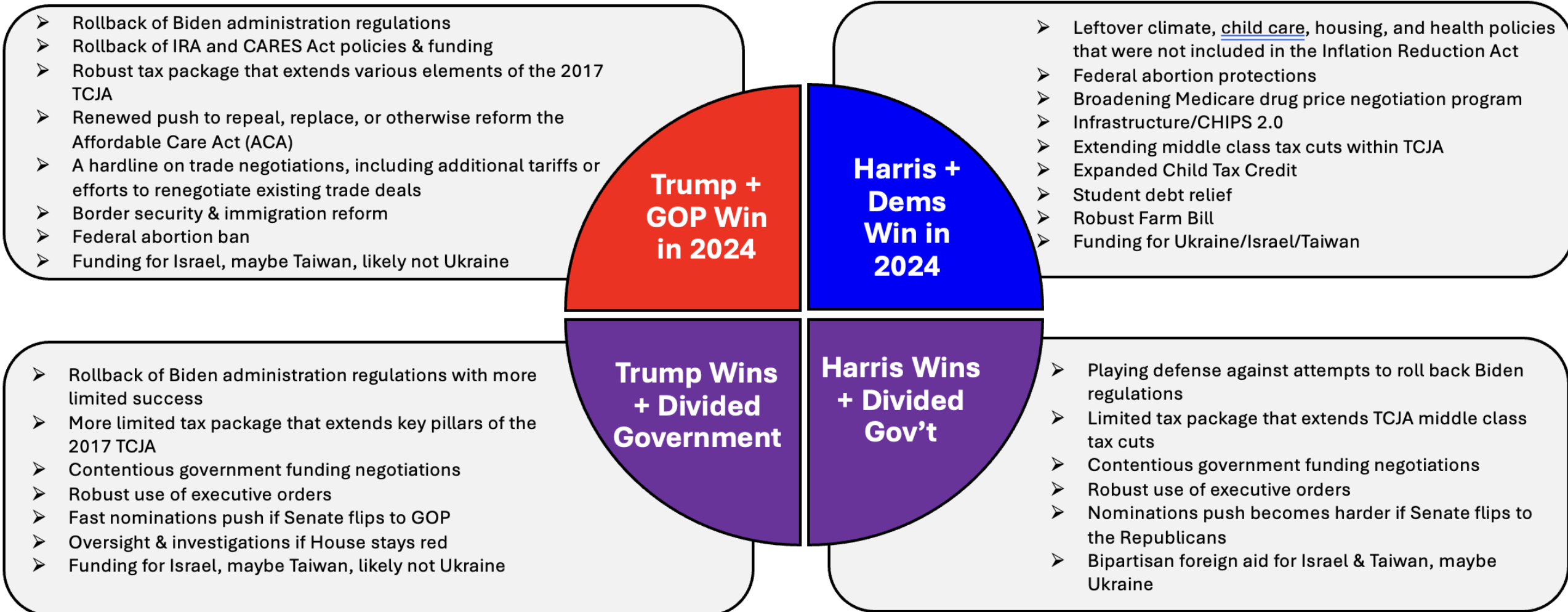


- The House battleground continues to take shape with near equal number of toss-up seats.
- VP Harris' nomination has stabilized many "vulnerable" Dem seats, and **improved Dems chances of netting 4 seat to win back the majority.**
- Too close to call, but **GOP defending 17 seats** – many in CA & NY - won by Biden to Dems' 5 won by Trump in 2020

2024 ELECTION SCENARIOS

President	House	Senate	Likelihood	Likelihood analysis
R	D	R	High ●●●●●	Presidential race is a toss up; Democrats have a chance to regain control of the House, but GOP will likely flip the Senate
D	D	R	High ●●●●●	Presidential race is a toss up; Democrats have a chance to regain control of the House, but GOP will likely flip the Senate
R	R	R	Medium ●●●●●	GOP has a chance to win control of Congress
D	R	R	Medium ●●●●●	GOP has a chance to win control of Congress, but it's less likely for Democrats to win the presidency and lose both chambers of Congress
R	R	D	Low ●●●●●	Democrats will struggle to retain Senate control; unlikely that GOP would win the presidency and House but fail to flip the Senate
D	R	D	Low ●●●●●	Democrats will struggle to retain Senate control; unlikely that GOP would win House control but fail to flip the Senate
R	D	D	Very Low ●●●●●	Highly unlikely for Democrats to lose the presidency but win both chambers of Congress
D	D	D	Very Low ●●●●●	Democrats are unlikely to win both chambers of Congress

FEDERAL POLICY IN 2025





FDA

- **MDUFA V is a MASSIVE industry investment totaling \$2B**
- **Hitting hiring targets, with approximately 25% of “new” hires internal to FDA**
- **FDA making progress on MDUFA V quantitative and qualitative goals**
- **Priority area of focus for FDA has been around the quality of Deficiency Letters**
 - Significant training, retraining and multiple audits to ensure review staff are including the justification for the deficiency in the communication to the sponsor
 - FDA met FY23 goal of 75% of deficiency letters include the justification (increased 5% year to 95% in FY27)
- **TAP was FDA’s top priority, industry agreed to pilot with MDUFA IV carry-over funds**
 - 54 devices enrolled; just expanded beyond cardio to ophthalmic, neuro and radiological – ortho in the new year
 - Have an opportunity to assess progress as part of MDUFA VI



AI/ML

- **POLICY TIGHTROPE:** How to unleash the full promise of AI tools while protecting the public against risk (and doomsday scenarios)?
- **CONGRESS TASK FORCES DEVELOPING ROAD MAP**
 - **SENATE “AI GANG”** led by Sen Schumer unveiled their \$32B framework “Driving U.S. Innovation in AI”
 - **House TASK FORCE on AI** created by Speaker Johnson and Dem Leader Jeffries still in fact-finding stage, report expected this fall
 - **NO SINGLE PLAN or “SUPER” Bill**, leave it up to the Committees to develop consensus approaches to key issues
- **FDA’s 30 YEARS OF EXPERIENCE:** FDA approved the first AI/ML-enabled device in 1995, and nearly 1,000 since then, and over 151 in the last eight months. **Software as a Medical Device (SaMD) and Predetermined Change Control Plan (PCCP)** enabled flexible approaches. Devices still must follow strict regulatory requirements for premarket review and post-market surveillance to ensure safety and efficacy.

CORE PRINCIPLES

- **MAINTAIN FDA’S PRIMACY AS CHIEF REGULATOR OF AI IN MEDICAL DEVICES**
- **SUPPORT NEW PAYMENT MODELS TO PROMOTE ADOPTION OF AI-ENABLED DEVICES & SOLUTIONS**
- **CONDITION 3rd PARTY INVOLVEMENT ON STRONG PROTECTIONS FOR COMPETITION**
- **DATA PRIVACY**



EMERGING CHEMICALS (EtO)

- EPA's NESHAP rule for commercial sterilizers went into effect on Friday, April 5th; sterilizers report compliance is on track. Meaningful shut-down, closures will likely start occurring 3Q25 to 4Q25.
- EPA is finalizing the follow-on pesticide registration – FIFRA Interim Decision (PID) – slated for December. The PID, as proposed, requires facility redesigns, revalidation of devices, and puts effective capacity limits due new worker requirements.
- EPA committed that the final pesticide registration will not undermine or interfere with the NESHAP
 - *"Since the issuance of the PID, OPP has been...collaborating with the office of Air and Radiation to ensure that the requirements of the FIFRA Interim Decision (ID) do not interfere with the requirements of this rule, and vice versa...OPP has been consulting regularly with other federal agencies and ...industry trade groups,, to discuss how best to harmonize the requirements of the FIFRA ID with the requirements of this rule, and to ensure that the operative standards,..., will protect both workers and...communities from the risks of EtO exposure while mitigating and managing any risk to the supply chain for sterile medical devices."*
- New concerns that EPA Leadership is reneging on their commitment on the PID through stringent future requirements; FDA is concerned.
- EPA investigating warehouses and off-site storage facilities for EtO sterilized products; considering future air control regulation



Questions?

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Learn more: <https://www.medicaldevices.org>

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