

2018 Midterm Elections and Implications for Health Care

December 3, 2018

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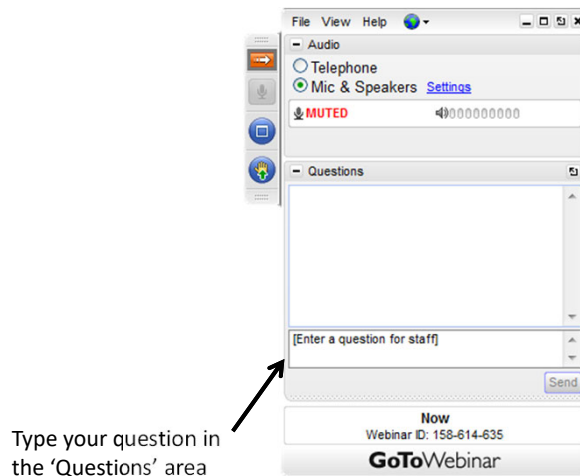
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How to Ask A Question



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Today's Speakers



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Topics

Midterm election results

Drug costs in the United States

Administration priorities

- Generic approvals
- Fiscal 2019 budget proposals
- President Trump's drug pricing "blueprint"

Pending bills in Congress

- Generic drug development
- Drug importation
- Medicare price negotiations
- Cost disclosures

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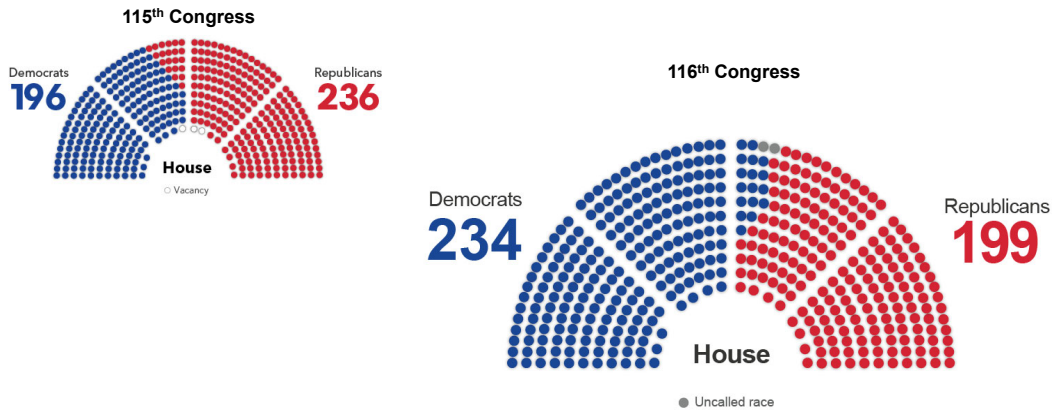
MIDTERM ELECTION RESULTS

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House Balance of Power

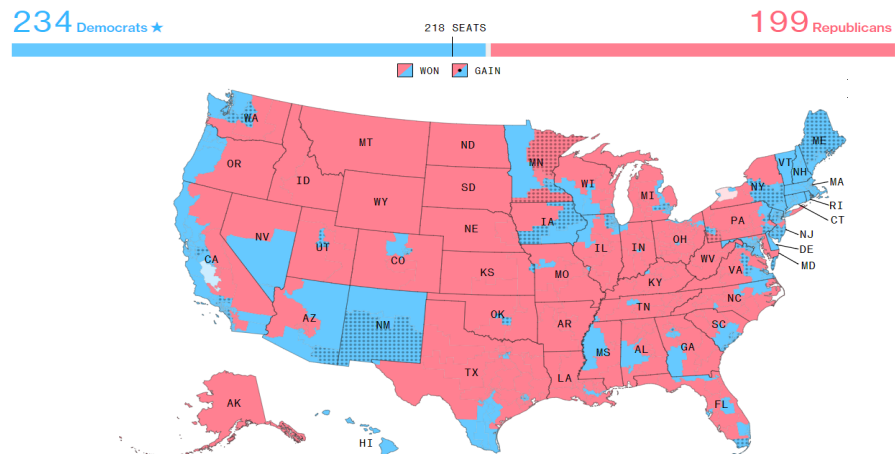
Democrats flip the House and will gain powerful committee gavels



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House Control

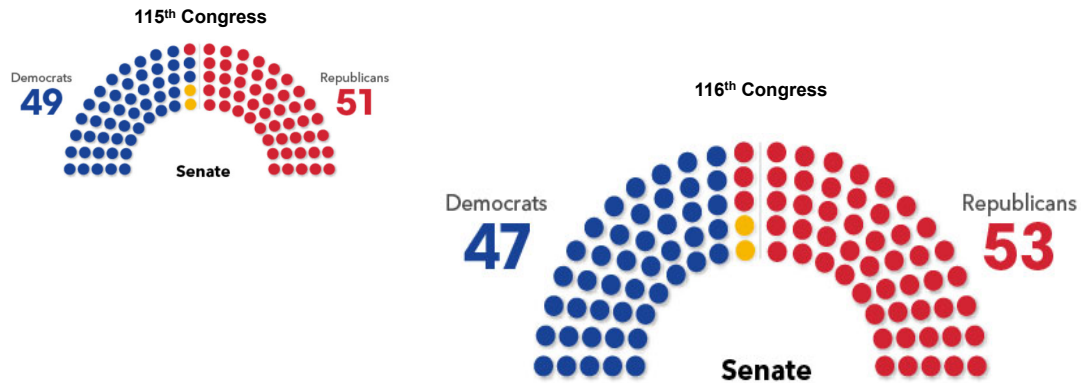


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Senate Balance of Power

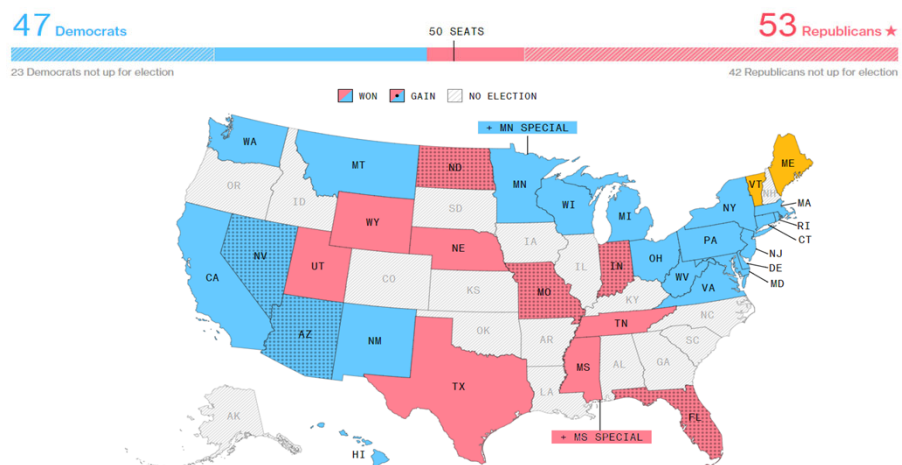
Senate Republicans maintain and expand their majority



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Senate Control



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2018 Midterm Election Insights

Many races fell along predictable party lines

- Unlike in 2016, the 2018 midterm elections saw relatively few surprises
- Republicans performed well where Trump's approval rating was over 50% and Democrats performed well where Trump's approval rating was below 50%

Some races were close, but Democrats pulled ahead in the House

- Early on, it seemed like Democrats would pick up 25-30 seats in the House, but not many more. However, Democratic candidates continued to claim victories through the night and as absentee votes were counted over the following days
- House Democrats will end the election with a 40-seat majority, slightly slimmer than the current Republican majority of 45 seats

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2018 Midterm Election Insights

Meanwhile, Republicans gained ground in the Senate

- Republicans had an highly advantageous Senate map and scored a solid win by picking up seats held by Senators Joe Donnelly (D-Ind.), Heidi Heitkamp (D-N.D.), Bill Nelson (D-Fla.) and Claire McCaskill (D-Mo.)
- Democrats won seats held by Sen. Dean Heller (R-Nev.) and retiring Sen. Jeff Flake (R-Ariz.)
- Republicans picked up a net gain of 2 seats, pushing their margin to 53-47
- Republicans needed a net gain to build a cushion against a difficult map in 2020

Why the divergence between the House and Senate? We see a potential urban-rural divide

- Senate races included rural and conservative states, while many House races encompassed suburban and urban areas. According to noted political analyst Charlie Cook, "it was like we were having two different elections in two different Americas."

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2018 Midterm Election Insights

Pharmaceutical costs may be an opportunity for bipartisan agreement

- The Trump administration will continue to pursue reforms in the President's "Blueprint to Lower Drug Prices"
- House Democrats will use control of the committees and floor to advance a set of drug pricing proposals of their own
- Democrats believe the President's proposals are too cautious, and the Republicans are likely to reject the most ambitious and aggressive Democratic proposals (e.g., importation, government negotiation in Part D)
- Democrats and Republicans may be able to find common ground on a handful of issues beyond Part B drug pricing reforms:
 - CREATES Act
 - Removing Medicaid rebate caps
 - Limiting "pay-for-delay" arrangements
 - Eliminating obstacles to value-based purchasing

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New chairmen and priorities in House health care committees

Energy & Commerce

Full Committee Chairman: Rep. Frank Pallone (D-N.J.)

Subcommittee on Health: Rep. Anna Eshoo (D-Calif.)

Ways & Means

Full Committee Chairman: Rep. Richard Neal (D-Mass.)

Subcommittee on Health: Rep. Lloyd Doggett (D-Texas)

Top three domestic issues for House Democrats:

- infrastructure
- ethics reform
- drug pricing

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ADMINISTRATION PRIORITIES

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U.S. spending on prescription drugs

Specialty drug prices and increased costs of older drugs have drawn scrutiny

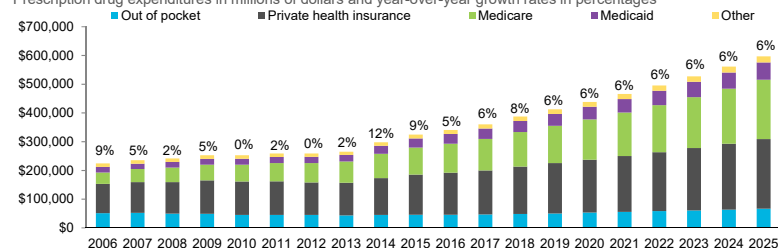
- » Drug companies say prices account for high cost of development

CMS projects that spending growth will decelerate in long run

- » Says new specialty drugs and ACA coverage expansion led to recent above-average growth

Drug Spending Expected to Grow at Slower Pace After Recent Spikes

Prescription drug expenditures in millions of dollars and year-over-year growth rates in percentages



Note: Data for 2016 through 2025 are projections. OECD – Organisation for Economic Co-operation and Development; CMS – Centers for Medicare & Medicaid Services
Sources: CMS [National Health Expenditure Data](#) (chart); [“Political Intrigue Continues to Overhang the Drug-Price Issue”](#) Bloomberg Intelligence, Jan. 31; [“Quicktake: Drug Prices”](#) Bloomberg News, June 23, 2017

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President Trump on prescription drug pricing

President said “prices will come down substantially” in 2018 SOTU address

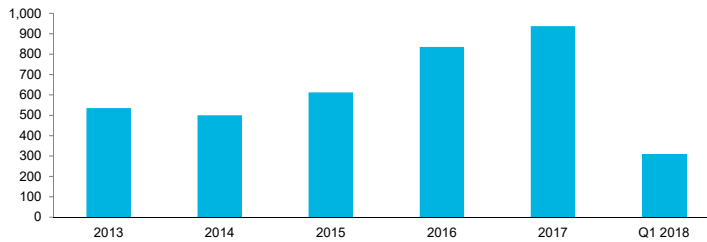
- » Touted record number of generic drug approvals by FDA in 2017

Trump has attacked high prescription drug prices since the election

- » President supported Medicare price negotiations but has since pulled back

FDA Generic Drug Approvals Continue to Reach Record Levels

Generic approvals and tentative approvals, by fiscal year



Notes: FDA – Food and Drug Administration; HHS – Health and Human Services Department
Sources: FDA Generic Drugs Program [activities reports](#), fiscal 2013-2018 (chart); [State of the Union address](#); “[Trump Sinks Pharma Stocks on Medicare Drug Price Negotiation](#),” Bloomberg News, Feb. 7, 2017; “[Trump FDA Nominee Wants Lower Drug Costs With More Generics](#),” Bloomberg News, March 29, 2017; “[Critics Say Trump’s Drug Price Talk Empty Without Actions](#),” Bloomberg Law, Jan. 31

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Administration’s fiscal 2019 budget included several Rx cost proposals

Changes intended to reduce costs under Medicare

- » Require Part D drug plans and pharmacy benefit managers to apply rebates from manufacturers to beneficiaries’ out-of-pocket costs
- » Reduce coverage requirements in Part D formularies from two drugs per class to one drug per class
- » Cap out-of-pocket costs for catastrophic coverage and provide free generic drugs to low-income beneficiaries
- » Modify payments for drugs under Part B and for hospitals under 340B program

Medicaid could test coverage and payment changes in some states

- » Would create a pilot program for as many as five states to set formularies and negotiate prices directly with manufacturers

Another proposal aims to increase competition among generic drugmakers

- » Would modify rules for exclusivity periods to allow other generic drugs to enter the market sooner

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Sources: White House fiscal 2019 [budget request](#); “[President Trump’s FY2019 Budget Request: Health Care](#),” Bloomberg Intelligence, Feb. 12

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Lawmakers have focused on increasing competition and transparency

Lawmakers are considering different ways of lowering drug prices

- » Bipartisan bills would end drugmaker tactics to delay generics from entering market and expand access to samples needed for testing generics
- » Several measures focus on increasing pricing transparency
- » Proposals to allow Medicare to negotiate drug prices or import drugs from abroad are largely backed by Democrats
- » Lawmakers could also look at preventing manufacturers from making minor changes to products to extend patents, known as “evergreening”

Congress has enacted recent laws to increase drug development

- » 21st Century Cures Act ([Public Law 114-255](#)) provided funding and other tools to spur drug development
- » FDA user fee reauthorization ([Public Law 115-52](#)) required FDA to expedite generic drug reviews

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President Trump’s drug pricing “blueprint” – key initiatives

Persuade other countries to pay more for Rx – or borrow their price controls

- » Create a Medicare Part B “international pricing index” model

Try to lower drug prices for Medicare

- » Pursue “value-based purchasing” arrangements
- » Make generic medicines free for some low-income Medicare beneficiaries*
- » Remove some protections from the “protected classes”

Add new regulations on drug advertisements

- » Require companies to publish the drug's list price in advertisements

Ban “gag clauses” for pharmacists

Put a halt to patent “games”

- » End “pay for delay” settlements

Fix the current rebate system

- » Consider whether rebates should be illegal under anti-kickback statutes

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PENDING BILLS IN CONGRESS

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Bills aimed at increasing generic competition have bipartisan support, but haven't advanced

Bill	Description	Sponsors
Preserve Access to Affordable Generics Act (S. 124)	Limit "pay-for-delay" settlements in which branded drug makers pay generic companies not to enter market for period of time	Sens. Amy Klobuchar (D-Minn.) and Charles Grassley (R-Iowa)
CREATES Act (S. 974, H.R. 2212)	Allow generic drug makers to bring civil action against brand-name companies that limit access to samples needed to test products	Sen. Patrick Leahy (D-Vt.) with 14 Democrats and 15 Republicans; Rep. Tom Marino (R-Pa) with 13 Democrats and 12 Republicans
FAST Generics Act (H.R. 2051)	Require drug makers to provide access to samples for testing and allow generic companies to sue if they are aggrieved	Rep. David McKinley (R-W.Va.) with 9 Democrats and 3 Republicans

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Drug importation bills for personal use have bipartisan support

Bill	Description	Sponsors
Safe and Affordable Drugs from Canada Act (S. 92, H.R. 1480)	Allow individuals to import prescription drugs from Canada for personal use	Late Sen. John McCain (R-Ariz) with 9 Democrats and 1 Republican, Rep. Chellie Pingree (D-Maine) with 5 Democrats and 4 Republicans
Personal Drug Importation Fairness Act (H.R. 934)	Allow individuals to import drugs from several specified countries that are the same as an FDA-approved prescription drug	Reps. Keith Ellison (D-Minn.) and Dana Rohrabacher (R-Calif.)
Affordable and Safe Prescription Drug Importation Act (H.R. 1245, S. 469)	Allow wholesalers, pharmacies, and individuals to import prescription drugs from Canada and other OECD countries	Rep. Elijah Cummings (D-Md.) with 28 Democrats; Sen. Bernie Sanders (I-Vt.) with 21 Democrats

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Medicare negotiation, other bills supported largely by Democrats

Bill	Description	Sponsors
Medicare Prescription Drug Price Negotiation Act (H.R. 242, S. 41)	Require HHS to negotiate drug prices for Medicare Part D	Rep. Peter Welch (D-Vt.) with 43 Democrats and 1 Republican; Sen. Amy Klobuchar (D-Minn.) with 13 Democrats
Medicare Drug Price Negotiation Act (H.R. 4138, S. 2011)	Require Medicare negotiations and establish formulary to set fallback prices; require rebates for drugs provided to low-income individuals	Rep. Elijah Cummings (D-Md.) with 19 Democrats; Sen. Bernie Sanders (I-Vt.) with 7 Democrats
Empowering Medicare Seniors to Negotiate Drug Prices Act (S. 1688)	Remove prohibition on HHS interference in price negotiations and setting formularies	Sen. Klobuchar with 34 Democrats
Stop Price Gouging Act (S. 1369, H.R. 2974)	Establish an excise tax on prescription drugs when prices spike	Sen. Sherrod Brown (D-Ohio) with 8 Democrats; Rep. Mark Pocan (D-Wis.) with 4 Democrats
S.1681 and H.R. 3536 (no short title)	Require individuals who conduct federally funded R&D to enter into "reasonable" price agreements	Sen. Bernie Sanders (I-Vt.); Rep. Peter DeFazio (D-Ore.) with 7 Democrats

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Other bills focus on disclosing how drug prices are set

Bill	Description	Sponsors
Prescription Drug Price Transparency Act (H.R. 1316)	Require pharmacy benefit managers to frequently update and disclose information used to determine pharmacy reimbursements	Rep. Doug Collins (R-Ga.) with 42 Republicans and 14 Democrats
Creating Transparency to Have Drug Rebates Unlocked Act (S. 637)	Require CMS to disclose pharmacy benefit managers' rebates and discounts; provide minimum portion to health plan sponsors	Sen. Ron Wyden (D-Ore.) with 4 Democrats
Stopping the Pharmaceutical Industry from Keeping Drugs Expensive Act (S. 1348)	Require drug makers to justify price increases of specified percentages to HHS and pay penalties if they don't	Wyden with 9 Democrats
Fair Accountability and Innovative Research Drug Pricing Act (S. 1131, H.R. 2439)	Require manufacturers to report specified price increases for products sold through Medicare and Medicaid to HHS	Sens. Tammy Baldwin (D-Wis.) and the late John McCain (R-Ariz.); Rep. Janice Schakowsky (D-Ill.) with 21 Democrats and 2 Republicans
Transparent Drug Pricing Act (H.R. 4116)	Require drug makers to report annually on costs, revenue, sales, and other information	Rep. Lloyd Doggett (D-Texas) with 32 Democrats

AMCP positions and points of engagement on drug pricing issues

- Congress must pass the Pharmaceutical Information Exchange Act (PIE Act, H.R. 2026) to allow payors and manufacturers to communicate health care economic information prior to FDA approval of a product. Passage of the PIE Act would provide the necessary legal underpinning for FDA's recent guidance, which largely follows AMCP's Partnership Forum recommendations.
- HHS should consider pharmacists as key stakeholders in improving outcomes and managing Rx costs
- CMS should carefully consider ways to effectively manage medications in Part B, transition coverage of select medications from Part B to Part D and carefully evaluate the impact of beneficiary out-of-pocket costs, access to care, and Medicare Advantage
- Part D plans should have full formulary flexibility to manage high-cost medications, including the classes of clinical concern ("protected classes")

AMCP positions and points of engagement on drug pricing issues

- CMS should adopt the Medicare Part D formulary coverage policy (coverage of one drug per class, versus two per class) as proposed in the President's FY2019 budget
- AMCP supports efforts to curb the inappropriate use of shared system Risk Evaluation and Mitigation Strategy program (REMS) to deter generic entry
- Food and Drug Administration (FDA) policies should promote biosimilar development and adoption
- Stakeholder collaboration and reexamination of current policies are needed to encourage VBC, including the need for a common definition of VBC, best practices, and legal and regulatory infrastructure to support VBC

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QUESTIONS?

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