
Coalition for Healthcare Communication Post-Election Conference

National Press Club

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What's ahead for 2019? Coalition issues and priorities

**Jon Bigelow
Coalition for Healthcare Communication**

**Post-Election Conference
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Who we are

- The healthcare communications field needs a voice at the table. That voice is the Coalition for Healthcare Communication.
- The Coalition promotes the free flow and availability of accurate and credible health information, to benefit society and individual patient care.
- The Coalition:
 - Keeps members informed: What is happening, what it means
 - Joins the dialogue, presenting our industry's side of the story
 - Mobilizes action where needed

Members

AAAA

American Academy of Family Physicians

AbelsonTaylor

Association of Medical Media

Beacon Healthcare Communications

Concentric Health Experience

Cross & Wild

Crossix Solutions

Everyday Health

Frontline Medical Communications

FCB Health

Havas Health & You

Haymarket Media

HMP

IPG

Juice Pharma

Massachusetts Medical Society

Omnicom Health Group

Pacific Communications

Publicis Health

Radius Medical Animation

ReachMD/US Health Connect

Reed Elsevier

Remedy Health Media

Slack

Springer

UBM Medica

Wolters Kluwer

What just happened?



Headlines

- A blue wave
 - Won House decisively (~ 235 seats)
 - Won popular vote (by 8.8m, 53% in House, 14m in Senate)
 - 49% turnout, highest for midterms since 1914
 - +7 governors, +7 state legislative chambers, +349 legislators
- GOP held the Senate
 - Margin of 2 or 3 (Mississippi runoff pending)
- To note:
 - House GOP may be less moderate
 - 22% (95) of Representatives are new
 - Only 9 states have split Senators
 - Only 1 state has split legislative chambers (plus Nebraska)
 - Presidential contenders stake out positions

Is gridlock good?

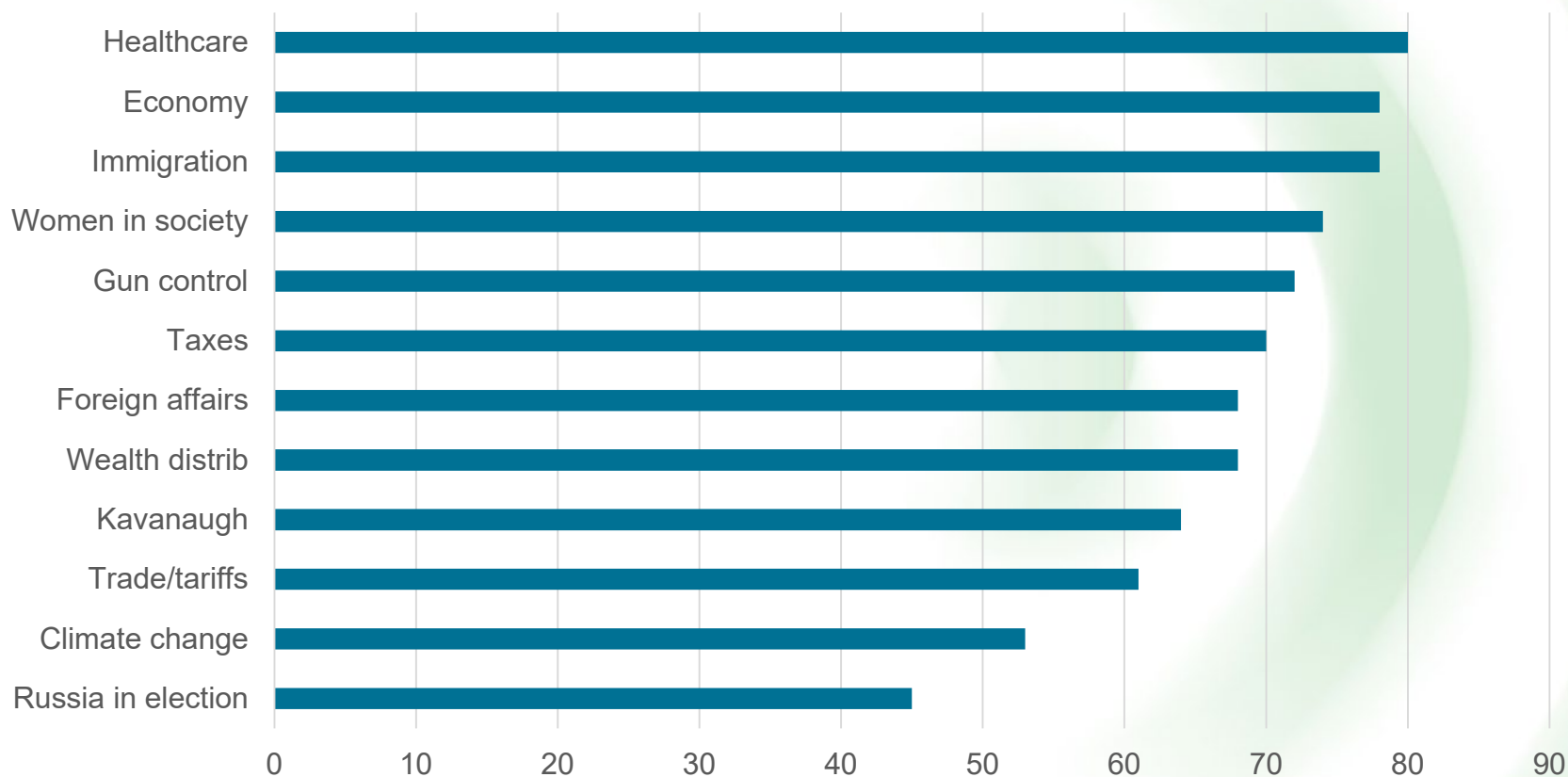
- **“A divided government—with the House and Senate controlled by different parties—is good for pharma”**
- Wall Street seems to think so....
- Don't bet on it!

Potential distractions

- Trump cabinet/staff shuffle
- Mueller investigation
- House investigations of Trump, Russia, etc.
- Any further SCOTUS vacancies
- Showdowns over budget (Dec. 7, Sept. 30)
- Any national or international crises
- Any economic slowdown

Healthcare was #1 voter concern in midterms

% saying Extremely/Very Important to your vote



Gallup Midterm Election Benchmark poll, conducted Oct 15-28, 2018

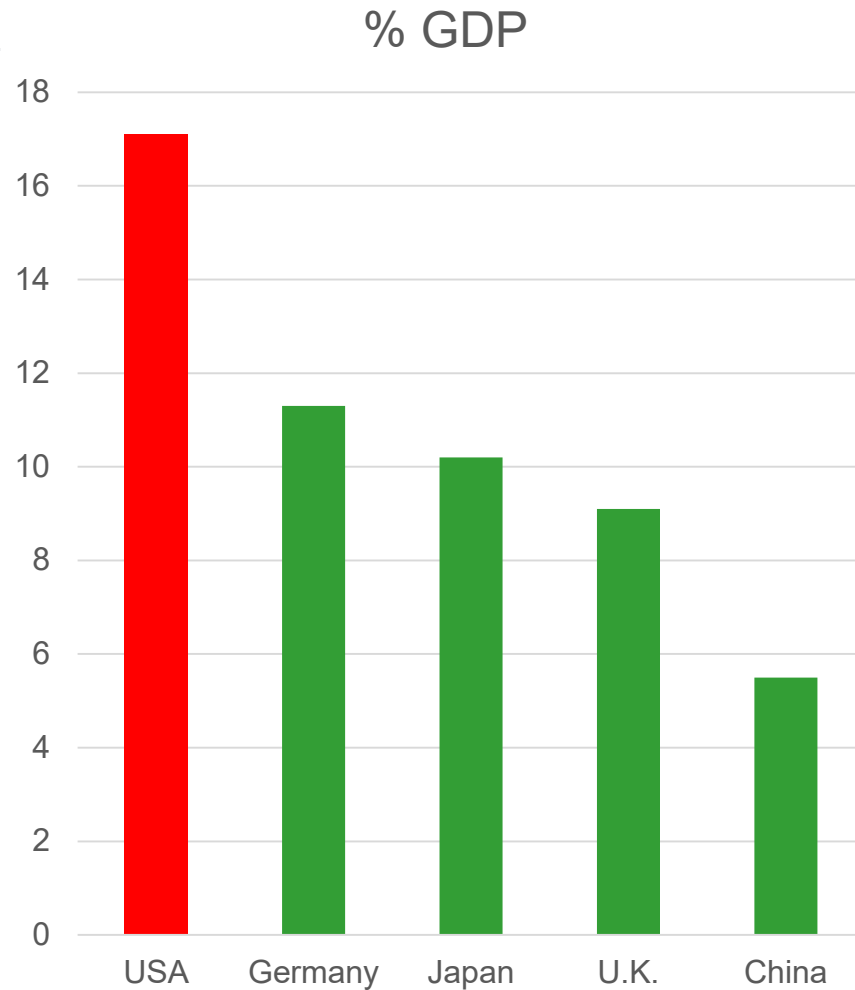
Key players in a divided government

- In the Senate
 - Leaders: McConnell and Schumer
 - HELP: Lamar Alexander (R-TN) still chair
 - Finance: Charles Grassley (R-IO) succeeds Orrin Hatch as chair
 - And running for President....
- In the House:
 - Leaders: Pelosi and McCarthy
 - Energy & Commerce cmte: Frank Pallone (health: Anne Eshoo)
 - Ways & Means health subcmte: Lloyd Doggett (D-TX)
 - Oversight committee: Elijah Cummings (D-MD)
- In the Trump administration
 - Possible departures or shifts?

5 areas to watch in 2019

- Drug prices
- Data privacy
- At the FDA
- Taxes
- Deregulation

The core problem, in brief



Drug price issue unites Republicans...

- Trump blueprint
 - Reduce roadblocks to generics and biosimilars
 - Put list prices in TV advertising
 - First Amendment issues
 - “Transparency” sounds good, but list price misleading
 - CMS comments process underway → final regulation
 - House and Senate may codify, fill in any gaps
 - PhRMA proposal to provide with context on websites
 - Impact on promotional mix?
 - International pricing index for Medicare Part B
 - “Demonstration project” for 50%: administrative overreach?
 - Fear this is a step toward price controls
 - Is premise valid? Other countries focus on value/price equation
 - Impact unclear

...and Democrats

- Hearings and “perp walk”
- Proposals in Congress
 - Medicare part D negotiate prices
 - If negotiations break down, issue “licenses” to avoid patents
 - 100 Democratic co-sponsors in outgoing House
 - Sanders-Khanna proposal
 - Strip patent rights on drugs determined “excessively priced”
 - Not just Medicare
 - CREATES Act: Prevent slow-walking generics
 - Prohibit “pay for delay”
 - Lloyd Doggett, Chuck Grassley support
 - Loosen cap on rebates offered on Medicaid drugs
 - Save \$3.8B; Michael Burgess (R-TX supports)
 - Importation from Canada
 - Banning DTC in first 3 years after approval

Expect action in 2019

- Political pressure
 - Many candidates ran against “big pharma”
 - Pelosi, McConnell, Schumer highlight problem on Sunday shows
 - Ad campaign to “hold them to their promises”
 - “National Coalition for Health Care”
 - Save money, helps with budget
 - HHS/CMS can do a lot without legislation
 - Proposals at state level
- Curtailing pharma profits
 - Were major beneficiaries of 12/17 tax bill
 - More profitable than other segments of health care ecosystem
 - Continuing price increases
 - Easy target
- Impact on pharma marketing and communications

Data privacy and marketing

- Data's potential—in practice, research, marketing
- Federal government reticent to regulate search and social media
- The anger is building
 - Repeated hacks of consumer information
 - Fake news
 - Cambridge Analytica and misuse of data in elections
 - Proliferation of online pharmacies
 - Tech leaders' halting responses at hearings
 - Public increasingly concerned over privacy and intrusive ads

Expect action in 2019

- European Union GDPR
 - Expands definition of personal data
 - Greater consumer consent including opt-in
 - Severe penalties, up to 4% of profits
- California Consumer Privacy Act (CCPA)
 - Effective 1/1/20—but...
 - Trailing 12-month data, so need take action for 1/1/19
 - Consumer right to know what collected, from where, what sold, to whom—and to say No
 - Applies even to smaller businesses
- Industry fears having 50 states set different rules
- Impact on pharma marketing and communications

At the FDA

- Scott Gottlieb methodically moving forward with agenda
 - Strong pace of drug approvals
 - Fine-tuning processes and org chart
 - Special approaches in key areas, eg antibiotics
 - Improving clinical trials, eg adaptive design, real world evidence
 - Enforcing “off-label” but in subtler ways
 - Research on clearer presentation of risks in DTC
 - Limitations on flavored e-cigs
- Supports Trump initiatives but stays out of line of fire
 - Restrictions on opioids
 - Limited-dose packaging, “comparative” approvals
 - Biosimilars action plan
 - Top 2019 priority is more generics
 - Positions FDA as following science, as part of solution
- We constantly monitor

Taxes

- Many ideas to add to the deficit...
 - Extend 2017 individual tax cuts
 - “10% tax cut for middle class”
 - Bipartisan support for infrastructure spending
 - Democrats want more for opioid issue, strengthen ACA
 - Trump wants more for defense and border wall
 - Special interests
- And no one wants to raise taxes...
- Yet the debt is growing and interest rates are rising
- So, how to claw back significant money?
 - Pharma could be a target
 - Pharma marketing could be a target
 - Danger: Ending deductibility of pharma marketing is “shovel ready”

Deregulatory environment

- Example: Revisiting Sunshine Act reporting of transfers of value
- House Appropriations Committee report
 - Encourages HHS Secretary to clarify that medical textbooks and reprints should be non-reportable under patient education exclusion
 - This consistent with Coalition's position
 - CMS originally took opposite position, required Open Payments reporting
- CMS issues RFI
 - What has been impact of TOV reporting requirements for distribution of educational materials and CME to physicians by industry
 - How materials eg journals and textbooks benefit patients
 - How to reduce unnecessary reporting while ensuring transparency
- Comments (including Coalition's) now being reviewed

What else?

- Opioids
 - Bipartisan issue at its core
 - Calls for more funding (MAT, mental health, research)
 - Investigation of manufacturers?
- Antibiotics for resistant organisms
 - 2012—longer market exclusivity for new antibiotics
 - REVAMP—12-month exclusivity, transferable to another product
 - Gottlieb—new payment models, eg pay subscription to access
- Legislation regarding surprise medical bills

Affordable Care Act in Congress...

- Legislative “repeal and replace” is dead
- Regulatory attacks have weakened but not destroyed the ACA
 - Short-term plans, Medicaid work requirements, end mandate, cut marketing, eliminate “navigators”
- In many ways, ACA more stable
 - More popular, enrollment holding
 - Premiums rise only 3.6% in 2019 (vs 30% last year)
 - Providers returning to market—no “bare” counties
- “Medicare for All”, “single-payer”, “public option”
- Until 2020, expect only tweaking at Congressional level

ACA in the states – and in the courts

- Medicaid expansion in the states
 - ID, NE, UT voted to expand Medicaid
 - KS, ME, WI elected pro-ACA governors
- Wild card: Texas v U.S.
 - Did ending mandate make entire law unconstitutional?
 - Warring “red” and “blue” AG’s
 - Includes Sen.-elect Josh Hawley
 - DOJ declines to defend Federal law
 - In Federal court, judge slow-walking opinion
 - Appeals likely

Fundamentals

- Unmet clinical needs
- Intensive R&D to develop therapies that save lives, enhance quality of life, reduce costs to healthcare system
- Healthcare system depends on well-informed providers, payers, and patients
- Communications, marketing, and education are as important as R&D, and provide significant value to healthcare system

It's up to us

- To state our value to the healthcare system and the emphasis we put on ethical, accurate work
 - Do not assume it is understood
 - Do not assume this makes no difference
- To be proactive
 - Communicate innovations to health care professionals and patients
 - Let Washington hear your voices
- To be truthful, transparent, and fully forthcoming
 - It's the right thing to do
 - It's the law
- To be alert
 - Watch for policy changes, new enforcement priorities
 - What's legal, appropriate, and expected is shifting
 - Public perceptions are shifting
- To be proud

Get involved!

- Join our Industry Leaders list
- Visit us at www.cohealthcom.org
- Follow us on SmartBrief for Healthcare Marketers
- Come to our events
 - Breakfast Briefing: Next = NYC, January
 - Rising Leaders Conference: Washington, May
 - Teleconferences when issues arise
- Contact me at jbigelow@cohealthcom.org