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Ingersoll &  
Rooney PC**

## Health Care Compliance Association-Pittsburgh Regional Conference: 2018 Federal Affairs Update

Michael Strazzella  
October 5, 2018

## Appropriations - FY 2018

- Deadline - September 30, 2018
- Continuing Resolution to Dec. 7<sup>th</sup> (Lame Duck)
- Minibuses
  - Energy-Water, Legislative Branch and Military Construction-VA
  - Interior-Environment, Financial Services, Transportation-HUD and Agriculture
  - Defense and Labor-HHS-Education
- Future of Appropriations Process – 2 year cycle?
- Bring back Earmarks

## 340B Drug Discount Program

- ASP minus 22.5% (cut 28.5%)
- Savings must be redistributed equally to hospitals covered under OPPS.
- Divisions among Pharma, Hospitals, Community Oncologists
- Legislation: Ranges from reversing the cut to transparency of dollars
- Lawsuits (AHA)

## Opioid Efforts (HR 6)

- How to address the Opioid Epidemic?
- House bill passed on June 22, 2018
- Senate bill passed the week of September 17<sup>th</sup>
- Topic Areas of HR 6
  - Treatment and Recovery
  - Prevention
  - Protecting Communities
  - Fighting Fentanyl
- Will it even help??????????

## Physician Fee Schedule – CY 2019

- Just to name a few provisions:
- Eliminates prohibition on same day visits
- E/M Documentation
  - Redundancy
  - Teaching Physician
  - Simplification
- RFIs
  - Interoperability
  - Price Transparency

## Stark Self Referral

- CMS Request for Information:
  - June 25<sup>th</sup> (comments were due by August 24<sup>th</sup>)
  - 20 separate topics
- Ways and Means Health Subcommittee
  - “Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program”
  - Issues related to compliance and barriers
  - How should it be modified

# Drug Pricing: White House Team

- Fulfilling campaign pledge to address drug prices
- To do so, needed “A” team at Department of Health & Human Services
  - Sec. Azar – former Eli Lilly President of U.S. Operations
  - Dan Best, Sr. Adv. For Drug Pricing Reform – former CVS Part D
  - John O'Brien, Advisor to the Secretary, Pharmacist and former Insurance Policy Advisor

Deep understanding of the drug pricing and supply chain

Working to implement the “low hanging fruit” first

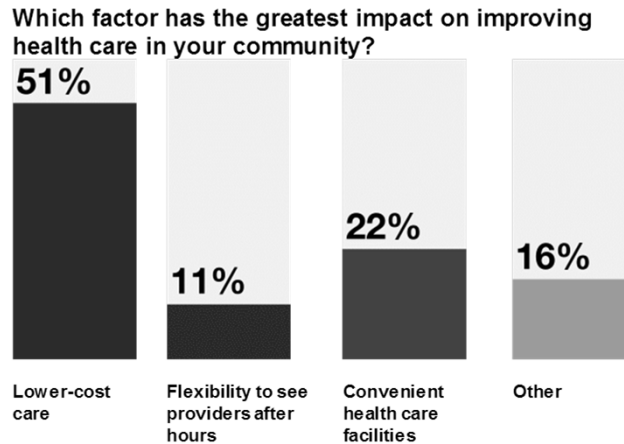
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## Blueprint to Lower Drug Prices and Reduce OoP Costs

- Divided into two categories:
  - Actions President may direct HHS to take immediately
  - Actions being considered by HHS – requested feedback
- Actions divided in the following areas:
  - Increased Competition
  - Better Negotiation
  - Incentives to Lower List Prices
  - Lowering Out-of-Pocket Costs

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## Public's View on How to help community



Source: CVS Health

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## Lower List Price (Transparency)

- List individual Rx price on CMS Drug Dashboard
- Durbin/Grassley amendment to LHHS Approps: \$1M to implement List Price incorporated in TV Ads
- Upcoming Rule regarding Medicare and Medicaid Drug Pricing Transparency
- Public Shaming – Pfizer (or was it?)

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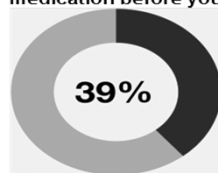
## Competition and Negotiation

- Step Therapy for Part B Drugs in Medicare Advantage – Begins Jan. 1, 2019
- Working group to examine Drug Importation
- Generic Drug Approvals since Blue Print released – “record number in July”
  - 2017: over 1,000 total
  - July 2018: 126 total
- CREATES Act and May public shaming of branded drugs impeding access to samples

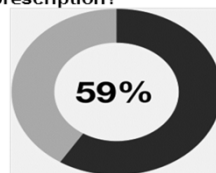
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## Out-of-Pocket Knowledge

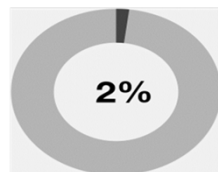
Do you typically know the out-of-pocket cost for a medication before you fill the prescription?



Yes



No



No opinion

Source: CVS Health

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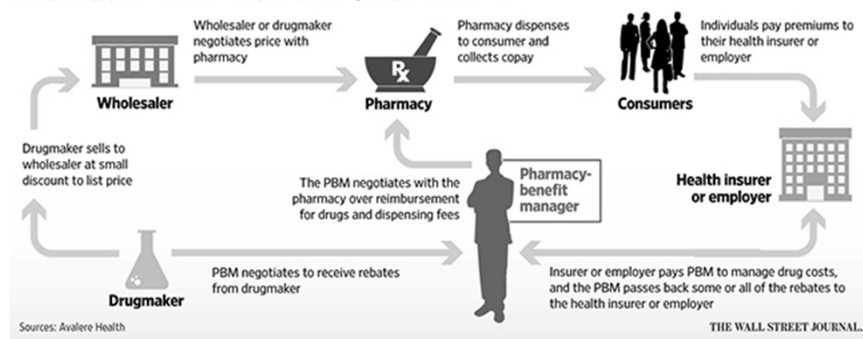
## Out-of-Pocket Costs

- Revoke pharmacy “gag clauses” for Part D- supportive of more expansive
- 340B – inpatient and outpatient ----big turf battle
- Lots of vague talk

## How the Industry views Drug Distribution

### How Drug Distribution Works

A complex supply chain determines how prescription drugs are paid for in the U.S.



# How the White House views Drug Distribution

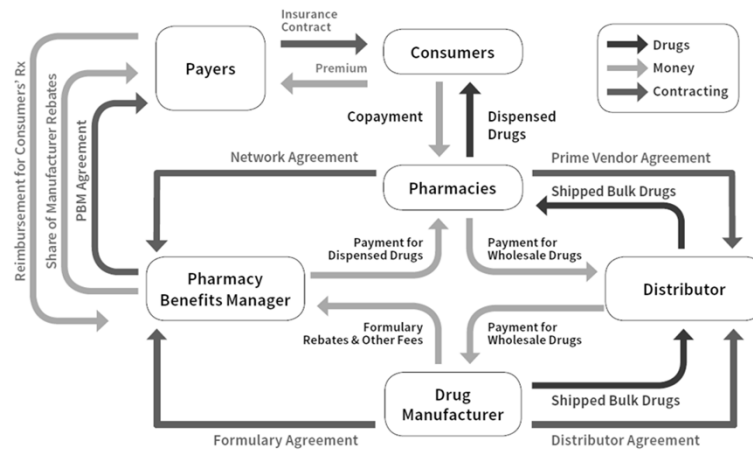


FIGURE 1

ADAPTED FROM: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channel Institute, January 2016.

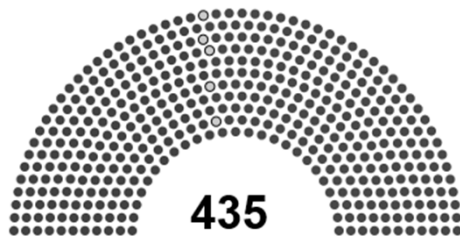
## PBM

- Political Landscape
  - White House
  - Congress
- PBM vs the World (almost)
- Rebates reduced costs in Part D by \$34.9B and w/out premiums ↑ 52% in 2018 (Oliver Wyman Consulting)
- "This study further confirms that drugmakers set and raise prices unrelated to the rebates they negotiate with PBMs. Drug companies keep raising prices even when rebates go down," said **PCMA President and CEO Mark Merritt**. "Simply eliminating plans' ability to negotiate price concessions would enrich drugmakers at the expense of patients, who'd not only face higher prices but higher premiums and out-of-pocket costs too."



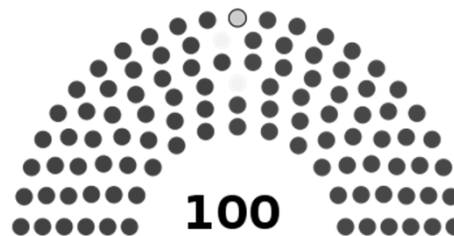
# 115<sup>th</sup> Congressional Party Breakdown

## House



193 Democrats - 237 Republicans - 6 Vacancies  
Democrats need a net gain of 22 seats to flip control of the House.

## Senate



49 Democrats (including 2 "Independents")  
51 Republicans  
Democrats need a net gain of 2 seats to flip control of the Senate

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## November Mid-Term Elections: House

- According to Cook Political Report, 11 Republican seats are "likely" or "lean" Democratic.
- Another 28 Republican Seats are "toss-ups".
- Currently, only one Democratic seat is in danger of flipping Republican (Pennsylvania 14); only 2 Democratic seats are "toss-ups".
- Nate Silver's FiveThirtyEight gives Democrats a 82.9% chance of winning control of the House; Republicans have a 17.1% chance of retaining control.

### GOP Seats Leaning Left



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## November Mid-Term Elections: House

Republican “Toss-Up” Seats

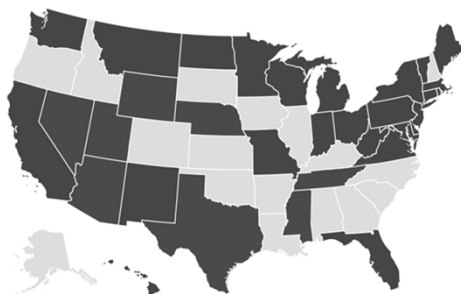
District	Incumbent
California 10	Rep. Jeff Denham
California 25	Rep. Steve Knight
California 39	OPEN
California 45	Rep. Mimi Walters
California 48	Rep. Dana Rohrabacher
Colorado 06	Rep. Mike Coffman
Iowa 03	Rep. David Young
Illinois 06	Rep. Peter Roskam
Illinois 12	Rep. Mike Bost
Kansas 02	OPEN
Kansas 03	Rep. Kevin Yoder
Kentucky 06	Rep. Andy Barr
Maine 02	Rep. Bruce Poliquin
Michigan 08	Rep. Mike Bishop
Michigan 11	OPEN
Minnesota 02	Rep. Jason Lewis
Minnesota 03	Rep. Erik Paulsen
North Carolina 09	OPEN
New Jersey 03	Rep. Tom MacArthur
New Jersey 07	Rep. Leonard Lance
New York 19	Rep. John Faso
New York 22	Rep. Claudia Tenney
Ohio 01	Rep. Steve Chabot
Texas 07	Rep. John Culberson
Texas 32	Rep. Pete Sessions
Virginia 02	Rep. Scott Taylor
Virginia 07	Rep. David Brat
Washington 08	OPEN

Democratic “Toss-Up” Seats

District	Incumbent
Minnesota 01	OPEN
Minnesota 08	OPEN

\*Not listed are another 27 Republican seats that “Lean Republican” – considered competitive, but with a slight advantage for Republicans; 2 Democratic seats are “Lean Democratic”.

## November Mid-Term Elections: Senate



- 35 Senate seats are up for election in 2018 (including special elections in Minnesota and Mississippi).
- Of the 35 Senate seats, 26 are currently held by Democrats – including in 5 states that Trump won by double digits.

## Senate: Competitive Seats

### TOSS-UP/POTENTIALLY COMPETITIVE SEATS

(in order of most competitive/likely to flip)

STATE	INCUMBENT	TRUMP 2016
NV	Dean Heller	-2.5%
AZ	Jeff Flake (retiring)	+3.6%
MO	Claire McCaskill (D-MO)	+18.7%
IN	Joe Donnelly (D-IN)	+19.1%
ND	Heidi Heitkamp (D-ND)	+35.8%
TN	Bob Corker (retiring)	+26.0%
WV	Joe Manchin (D-WV)	+42.1%
MN	Tina Smith (D-MN)	-1.5%
FL	Bill Nelson (D-FL)	+1.2%
TX	Ted Cruz (R-TX)	+9.0%
OH	Sherrod Brown (D-OH)	+8.1%
MT	Jon Tester (D-MT)	+20.5%
WI	Tammy Baldwin (D-WI)	+0.7%
PA	Bob Casey (D-PA)	+0.7%
MI	Debbie Stabenow (D-MI)	+0.2%
NJ	Bob Menendez (D-NJ)	-14.1%

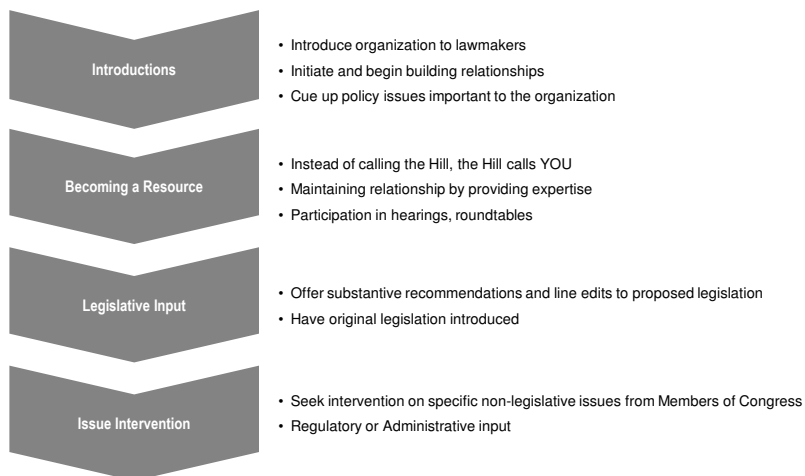
## Pennsylvania's Most Watched List

- Seven Freshman Representatives
  - New 4<sup>th</sup> District, Meehan, Costello, Dent, Barletta, Shuster, Murphy
  - Rep. Rothfus vs. Rep. Conor Lamb
- Other matchups – Sleepers?
  - Rep. Carthwright vs. John Chrin
  - Rep. Kelly vs. Ron DiNicola
  - Rep. Perry vs. George Scott

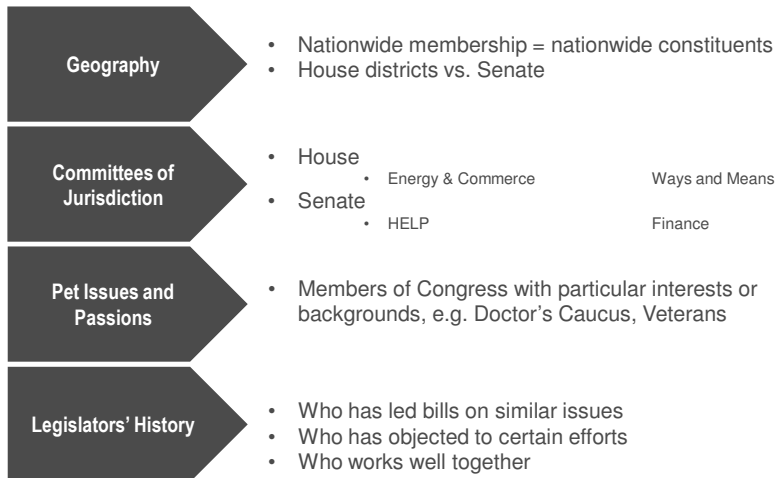
# What is “lobbying”

- ✓ **Education!!**
- ✓ **Substantive policy expertise**
- ✓ **Political insight and access**
- ✓ **Creative problem-solving**
- ✓ **Play nice**
- ✓ **Ethical obligations**

# Phases of GR



## Who do you engage?



## 3 Actions to Take to Maximize your Agenda



**Advocate**



**Collaborate**



**Ideate**