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# **What's ahead for 2019-2020? Coalition top issues and priorities**

**Jon Bigelow**

Executive Director, Coalition for Healthcare Communication

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# Who we are

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- 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

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**AAAA**  
*American Family Physician*

**AbelsonTaylor**

**Association of Medical Media**

**Beacon Healthcare Communications**

**CloserLook**

**Concentric Health Experience**

**Cross & Wild**

**Crossix Solutions**

**DMD Marketing**

**Everyday Health**

**Frontline Medical Communications**

**Havas Health & You**

**Haymarket Media**

**HMP Global**

**Intouch Group**

**IPG [Weber Shandwick, McCann, FCB]**

**Juice Pharma**

**Massachusetts Medical Society**

**Omnicom Health Group**

**Pacific Communications**

**Publicis Health**

**Reed Elsevier**

**Remedy Health Media**

**Slack**

**Springer**

**UBM Medica**

**Wolters Kluwer**

# 5 key issues we're watching closely

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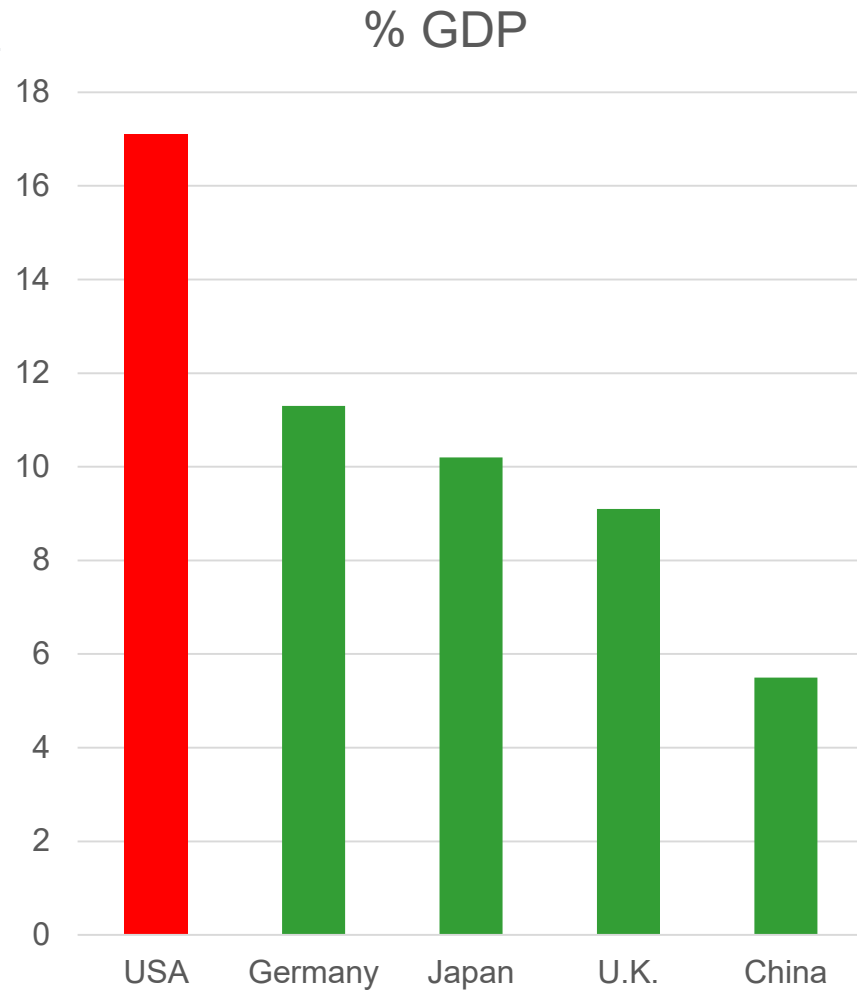


# Innovative, lifesaving drugs—but...

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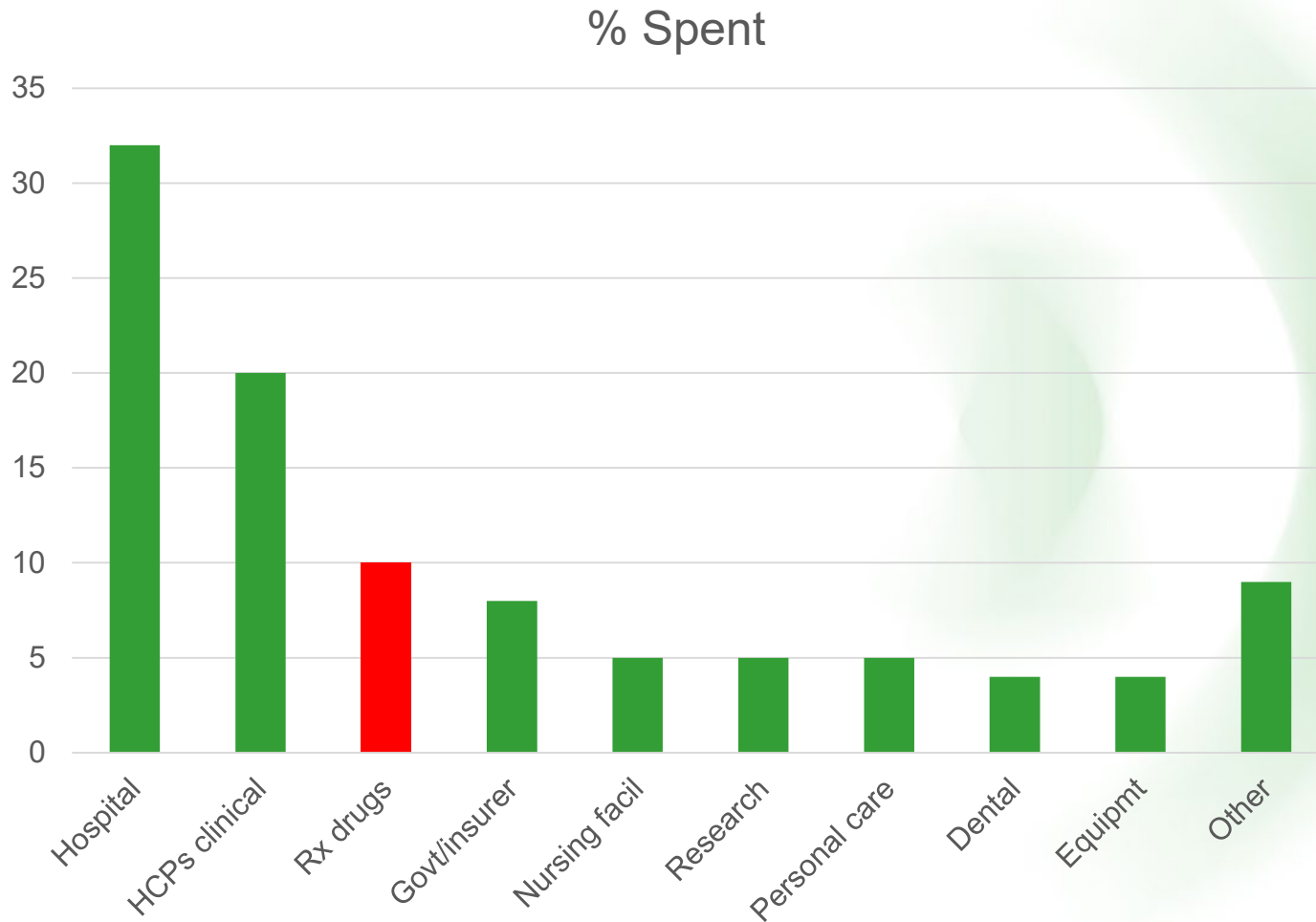
- Profound skepticism of pharma
  - Big tax cuts
  - More profitable than others
  - Continuing price increases
  - More visible to consumers
- Skepticism of pharma marketing
  - Belief that too much spent on DTC
  - Turing/Valeant, and now Purdue/Insys
- Fear of expensive therapies to come
- Intense political pressure
  - Candidates ran against “big pharma”
  - Save money, help with budget
  - Rare area for bipartisan agreement

# The core problem, in brief





# Where is our \$3.2 trillion health bill spent?



# Drug price issue unites the parties

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- Trump blueprint
  - Put list prices in TV advertising
  - Reduce roadblocks to generics and biosimilars
  - International pricing index for part B drugs
  - Bar PBMs/insurers from rebates on drug prices
- Among the many legislative proposals
  - CREATES Act re: slow-walking generics
  - Prohibit “pay for delay”
  - Part D negotiate prices (if “bad faith”, void patents)
  - Sanders-Cummings: Tie drugs to 5 other nations, threaten patent
  - Sanders-Klobuchar: Allow importation from Canada
  - Wyden and Sanders-Smith bills to cap OOP costs
- Oversight hearings and “perp walks”



# Coalition concerns

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- Clearly, need some way to control health care costs
- Drug prices are part of the problem
- Not all of the ideas make sense, some pose legal problems
- Outside our mission: How drugs are priced
- Within our mission: When “solutions” impede communications
  - Compelled speech
  - Restricted speech
  - Bans on DTC
  - Marketing tax

# Taxes

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- Many ideas to add to the deficit...
  - Extend 2017 individual tax cuts
  - Bipartisan support for infrastructure spending
  - Democrats want more for opioid issue, ACA
  - Trump wants more for defense and border wall
  - Special interests
- And no one wants to raise taxes...
- Yet the debt is growing
- 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”
  - Shaheen-Warren: “End Taxpayer Subsidies for Drug Ads Act”

# Data privacy and health

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- Data's potential
  - In practice, public health, research, transparency, marketing
- Potential weak links in the health data privacy chain
  - Reliance on vendors' procedures
  - "One hack away"
  - New ways to use data (artificial intelligence)
  - Re-identifying de-identified data (location data + machine learning)
- U.S. has been the outlier
  - OUS, consent-based framework, eg GDPR
  - U.S., regulation by sector; heavy reliance on self-regulation
  - Burden on consumers:
    - Review terms and conditions, within time limit, then opt in, then return to control privacy settings
    - Is this "informed consent"?

# Action is coming—but what kind?

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- Public and Congress frustrated
- Hard to pass anything quickly in Congress
- Pressure from deadline in California and other states
- Multiple directions
  - Follow GDPR or CCPA model
  - “Privacy for America” model
  - Wyden: Annual transparency report, jail time if CEO hides or lies
  - Schatz: Techco-supported, focus on data processing
  - Rubio: Have FTC draft regulations, pre-empt states
- How will regulation affect our industry?
  - Health data’s special characteristics
  - Advantage for agencies with scale?

# At the FDA

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- Under Scott Gottlieb, bright spot in Washington universe
  - Strong pace of drug approvals
  - Special approaches in key areas, eg antibiotics
  - Improving clinical trials, eg adaptive design, real world evidence
  - Fine-tuning processes and org chart
  - Research program helps guide promotion enforcement
  - Restrictions on opioids, eg limited-dose packaging
  - Positions FDA as following science, as part of solution
  - Stronger funding, not badly hurt by lengthy shutdown
- Starting to roll out 2019 priorities
  - Tobacco and vaping
  - Framework on Real World Evidence
  - Biosimilars action plan

# What next for the FDA?

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- Maintain the momentum on Gottlieb initiatives?
- Ned Sharpless as Acting Commissioner
  - Communication skills
  - Relationships inside Trump administration and on Hill
  - Clout
- Who will be permanent Commissioner, and when?
- Looking ahead to budget battles, PDUFA, etc.

# Deregulatory environment

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- Example: Revisiting Sunshine Act reporting of transfers of value
- Coalition, with allies including *New England Journal* and Reed Elsevier, working both Hill and CMS to reverse requirement to report industry provision of textbooks and journal reprints under Open Payments
- CMS considering next steps based on responses to October 2018 RFI
  - Distracted by other priorities
  - Reversing current rule likely requires formal rulemaking, delaying progress for several months
- Hill action possible as amendment to other health-related bill
  - Rep. Burgess, Rep. DeFazio, Sen. Barasso among supporters



# What else?

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- Pharmaceutical Innovation Exchange (PIE) Act
  - Exchange of information ahead of drug approval to aid contracting
  - Formulary decisions made 12-18 months ahead
- Hearings on pharma
  - Fallout from Purdue investigations
- Status of Affordable Care Act
  - Weakened, but more stable and popular
  - “Medicare for all”, or “for more”, public option
- ACA and *Texas vs U.S.* case
  - Implications for Sunshine Act, innovation centers, Medicare, etc.
- Issues and candidate positioning during Presidential campaign

# The Coalition serves you

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- Monitoring what's happening in DC and the states
- Working with partners and allies
- Keeping members informed
- Joining the dialogue, present our side of the story
- Mobilize action where needed

# Fundamentals

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- 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, education as important as R&D, provide significant value to healthcare system

# It's up to us

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- 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—with clients, Members, family, and friends
- To be truthful, transparent, and fully forthcoming
  - It's the law – and the right thing to do
- To be alert
  - Watch for policy changes, new enforcement priorities
  - What's legal, appropriate, and expected is shifting
- To be proud

# Get involved!

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- Join our Industry Leaders Alert list
- Fill in your evaluation form
- Visit us at [www.cohealthcom.org](http://www.cohealthcom.org)
- Follow us on SmartBrief and LinkedIn
- Contact me at [jbigelow@cohealthcom.org](mailto:jbigelow@cohealthcom.org)