

# Regulatory & Compliance in POC Marketing, Health Policy & Washington

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Healthcare Communications

# Coalition for Healthcare Communication

- *The healthcare communications industry's voice at the table*
- *The Coalition promotes the free flow and availability of accurate and credible health information, to benefit society and individual patient care*
  - *Keeps members informed*
  - *Presents our industry's side of the story*
  - *Mobilizes action where needed*

4As	American Family Physician
Abelson Taylor	Association of Medical Media
Beacon Health Communications	CloserLook
Concentric Health Experience	Cross & Wild
Crossix Solutions	DMD Marketing
Everyday Health	Frontline Medical Communications
FCB Health	Havas Health & You
Haymarket Media	HMP Global
Intouch Group	Interpublic Group
Massachusetts Medical Society	Omnicom Health Group
Pacific Communications	Patient Point
Publicis Health	RELX Group
Remedy Health Media	Slack
Springer	Swoop
Wolters Kluwer	

# Three issues that matter to you

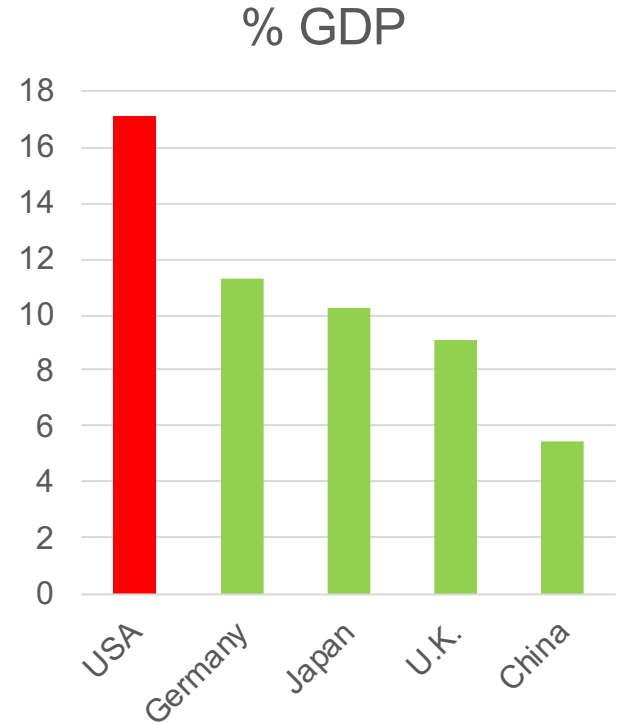
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- **Reining in drug prices: Beware the side effects!**
- *Data privacy and security: What will new regulations look like?*
- *FDA leadership and direction: Drift ahead*

# The problem, in brief

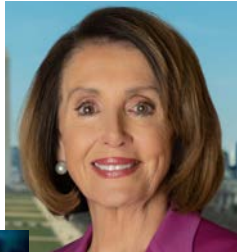
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- *Profound skepticism of pharma*
  - *Major beneficiaries of 12/17 tax bill*
  - *More profitable than others*
  - *Continuing price increases*
  - *Most visible to consumers*
- *Leads to skepticism of pharma marketing*
- *Political pressure*
  - *Candidates ran against “big pharma”*
- *Save money, helps with budget*
  - *Rare area for bipartisan agreement*
- *Fear factor: Expensive gene therapies*



# Pricing issue unites the parties

- *Trump blueprint: Prices on TV; international pricing; PBM rebates*
- *Senate pricing plan:*
  - *Cap OOP at \$3,100; price negotiations; reimportation*
- *House pricing plan*
  - *Cap OOP at \$2,000; negotiate on 25 - 250 drugs; claw back price hikes; international pricing*
  - *CBO: saves \$345B in 7 years; PhRMA: “nuclear winter”; progressives want more*
- *Other proposals*
  - *Prevent slow-walking generics, prohibit “pay for delay”*
  - *If “bad faith” or “excessive”, strip patent rights (Sanders, Cummings)*
  - *“March in” if price excessive (Buttigieg, Warren, Sanders, Harris)*
- *Plus: 51 laws in 33 states YTD*



# What to watch for

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- *Clearly, need to control health care costs*
- *To do so, must consider all cost drivers*
- *Drug prices an important part of the problem*
- *Not all of the ideas make sense, some pose legal problems*
- *Be wary of “collateral damage” impeding health communications*

# Example: “Compelled speech”

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- *FDA monitors messages: “Accurate and non-misleading”*
- *Trump proposal: Require list prices in TV drug advertising*
  - *Highly misleading, may deter patients talking with HCPs*
  - *First Amendment issues: Compelled speech*
  - *CMS appealing court ruling*
  - *Current version: Not POC*
- *Colorado HB19-1131*
  - *Include WAC of promoted drug and up to 3 generics for indication*
  - *Same practical and First Amendment flaws as CMS rule*
  - *Debate was about detailing—but vague wording on scope*
  - *Does it cover journals? POC?*
- *Value in discussing typical prices, more context on pricing*

# Example: Unequal treatment of taxes

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- *Many ideas to add to the deficit, no one wants to raise taxes...*
- *So, how to claw back significant money?*
- *Ending deductibility of pharma marketing expenses*
  - *Warren, Sanders, Harris, Klobuchar all favor*
- *Issues*
  - *Not just “advertising”: Most proposals include POC*
  - *Marketing informs HCPs and patients about new therapies*
  - *Deductible expense for over 110 years*
  - *Legal issue if one category singled out*
- *Greatest risk: 2020 budget, tax extender bills, debt limit*



# Example: Deregulatory initiatives

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- *DHS “Regulatory Sprint to Coordinated Care”*
- *Potential changes in anti-kickback rules*
- *Possible implications for POC?*
  - *Possible new safe harbor for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency*
- *Comments open until end of December*

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- **Data privacy and security: What will new regulations look like?**
- *FDA leadership and direction: Drift ahead?*

# A sea change

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- *Data's potential*
  - *In practice, research, public health, marketing*
- *Federal government reticent to regulate search and social media*
- *The anger is building*
  - *Repeated hacks of consumer information*
  - *Fake news*
  - *Cambridge Analytica*
  - *Tech leaders' halting responses at hearings*
  - *Antitrust concerns*
  - *Surveillance*
  - *Genetic information*
  - *Artificial intelligence*

# 2018-19: Empowering the consumer

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- *European Union GDPR*
  - *Expanded 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 (using trailing 12-month data)*
  - *Right to know what collected, from where, what sold, to whom—and to say No*
  - *Law written hastily, internal contradictions*
- *Industry moving to comply with GDPR and CCPA*
  - *Fears having 50 states set different rules*
  - *Many presume Federal legislation would take similar approach*

# The U.S. is the outlier

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- *OUS, move toward consent-based framework*
- *In U.S., regulation by sector*
- *Heavy reliance on self-regulation*
- *Burden is on consumers:*
  - *Review lengthy and abstruse terms and conditions, often in a time limit, then opt in, and then return to control their own privacy choices*
  - *Most click “I accept” for everything: Is this informed consent?*
- *Recognition that Federal regulation needed*
- *Growing interest in a new paradigm*

# 2020: Shift burden to government?

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- *Thesis:*
  - *Since few consumers can know the details of multiple privacy regimens at different sites to give “informed consent”, government should establish basic privacy parameters*
- *“Privacy for America” initiative*
  - *Data Protection Bureau; establish rules for data collection, use; identify certain practices as “per se unreasonable”; define process for designating additional practices unreasonable; rigorous safe harbor program*

# Pressure to act

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- *CCPA is now the de facto standard*
  - *Are your vendors compliant? Are you?*
  - *But uncertainties on implementation and penalties*
- *Bipartisan concern but hard to pass anything*
  - *Lack of expertise in Congress and FTC, complexity, ramifications of mistakes*
- *Multiple directions to consider*
  - *Follow GDPR or CCPA*
  - *Wyden: Annual transparency report, jail time if CEO lies*
  - *Schatz, 15 co-sponsors: Tech-supported, focus on data processing*
  - *“Privacy for America” model*
- *Can this be done in 2020?*

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# As of last March...

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- *Scott Gottlieb's activist agenda...*
  - *Record pace of drug approvals*
  - *Special approaches in key areas, eg antibiotics, generics, biosimilars*
  - *Fine-tuning processes and org chart*
  - *Improving clinical trials, eg adaptive design, real world evidence*
  - *Enforcing "off-label" but in subtler ways*
- *Supported by unusual skillset*
  - *Insider knowledge, personal experiences*
  - *Tech-savvy communicator*
  - *Supported Trump initiatives but stayed out of line of fire*
  - *Positioned FDA as following science, as part of solution*



# Who's next?

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- *Ned Sharpless as Acting Commissioner*
  - *Communication skills, relations at HHS and on Hill, ?s on clout*
  - *Endorsed by 5 former commissioners*
- *Decision looms*
  - *Long wait is not a vote of confidence in Dr. Sharpless*
  - *Azar, Trump considering others*
  - *Dr. Stephen Hahn; Dr. Brett Giroir; Dr. Alexa Kimball*



# What's next?

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- *In past, disruptive candidates considered*
- *Whomever chosen, confirmation battle ahead*
- *Risk of period of drift at FDA*
  - *Precedent under Bush 43*
  - *Hamburg-Califf-Gottlieb era of revitalization*
  - *Losing key personnel, difficulties in hiring*
  - *Budget battles, PDUFA*
- *Maintain the momentum on Gottlieb initiatives?*
  - *“Action plans on everything”*
  - *Likely continue current approach on promotional messaging*
  - *Could have implications for drug approvals*

# Key takeaways

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- *Despite impeachment battles, both parties want to show results on drug pricing—and this carries risks for marketing*
  - *POC: Watch compelled speech, taxation, deregulation initiatives*
- *New regulation of data privacy and security is highly likely, and may put guardrails around marketing activities*
  - *For now, CCPA is de facto standard*
- *After an activist era, the FDA may be headed for a period of drift*
  - *Most immediate implications are for drug approvals*

# Get involved!

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- *Join our mailing list*
- *Visit us at [www.cohealthcom.org](http://www.cohealthcom.org)*
- *Contact me at [jbigelow@cohealthcom.org](mailto:jbigelow@cohealthcom.org)*