

Healthcare Policy In Washington: Entering The 2020 Campaign Cycle

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Rising Leaders Conference on Healthcare Policy

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November 15, 2018

FDA Office Of New Drugs Director Search Nearing Completion; Deputy Director Peter Stein Remains Likely Choice

FDA's Center for Drug Evaluation & Research is wrapping up its two-year search for a permanent director of the Office of New Drugs, with an official announcement expected in early December.

While no announcement has been made either internally or outside FDA, the current Office of New Drugs deputy director, Peter Stein, appears poised to become full director.

In many ways, Stein is the obvious choice. As deputy director of OND for the past two years, he is well-tuned to the current structure and leadership within the review offices and divisions – and he has worked closely with CDER Director Janet Woodcock on the design of the planned extensive reorganization and “modernization” of the Office of New Drugs.

Woodcock has been leading both the search and OND itself since the retirement of long-time director John Jenkins in January 2017. Woodcock is understood to have interviewed several candidates for the position, eventually narrowing her search down to Stein and an industry executive. In choosing Stein, Woodcock is going with a previous recruit from outside the agency (Merck) who has had time to make the key connections and adjustments to working inside government.

By many outside accounts, Stein is thoroughly enjoying his time in government service – a sentiment he himself strongly articulated during a panel discussion on the “New OND” at the fourth annual Biopharma Congress on November 14. When asked, Stein declined to comment on whether he would like the top job at OND, but expressed enthusiasm for his current position, and added that he expects to close out his career at FDA. (He also noted that he has no plans to end his career soon.)

In one sign that an announcement may be imminent, Woodcock's colleague, Oncology Center of Excellence Director Richard Pazdur, commented twice during the Biopharma Congress and the Friends of Cancer Research annual meeting the day before that that she was “down to one job.” That, of course, is not quite official yet, but an internal OND town hall, initially scheduled for November 5 but postponed for a date in December, could provide an opportunity for leadership to announce both an update on the modernization process -- and, perhaps, the agency's pick to lead the office.

Stein is still relatively new at FDA: he joined the agency just two years ago from Merck Research Laboratories, where he was VP for late-stage development, diabetes and endocrinology. The appointment was considered a big win for the agency, which has had trouble attracting and retaining candidates from industry. (See our November 8, 2016 note, [FDA Office of New Drugs Fills Deputy Position From Outside: Merck's Stein Brings Industry Experience In Endocrinology](#).)

Stein was tested early as deputy director of OND: he was still settling into his job when Jenkins, his direct supervisor, announced his move to the private sector just a few weeks after Stein joined the

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Drug Pricing: *The Health Policy Priority*

Legislative Agenda for 116th Congress

HHS Administrative Reform

DTC Pricing Rule is Out – What Comes Next?

Medicare for All: Is It Possible?

What's Next For The Affordable Care Act

State of The FDA

Gottlieb's Legacy

What Will The Sharpless Era Look Like?

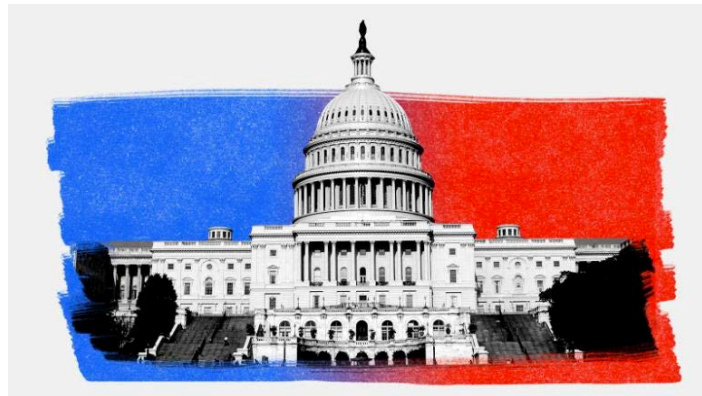
House Flips to Democrats, Hearings Follow

- Drug pricing, drug pricing, drug pricing
- Protect ACA pre-existing conditions
- PBM/rebate reform



What's On the Table: Incremental change on drug pricing, measures to shore up the ACA

What's Not: Entitlement reform or outright repeal of the ACA



Medicaid Expansion In Three GOP-Led States

- Ballot initiatives passed in Idaho, Utah and Nebraska

Gubernatorial Party Change Leads To Expansion

- Maine Gov. Janet Mills' (D) top priority
- Expansion approved by CMS in April

Democratic Gubernatorial Wins Could Lead To Future Expansion

- Wisconsin and Kansas had initially resisted expansion

Medicaid Expansion In 37 States Plus D.C.

- 13 states are still hold-outs

All in, 500K+ more beneficiaries could join Medicaid ranks...but work requirements could affect numbers.

What is Likely to Happen:

- ✓ Opioid package – as soon as this summer: October 24, 2018
- ✗ OTC user fee program and monograph reform (likely opioid rider)
- ✓ Animal drug user fees (likely opioid rider): 8/14/2018
- ✓ More congressional hearings on drug pricing

What Could Happen:

- Federal “Right to Try” legislation passed
- ✗ CREATES Act (access to generic samples)
- ✗ Action on 340B drug discount program

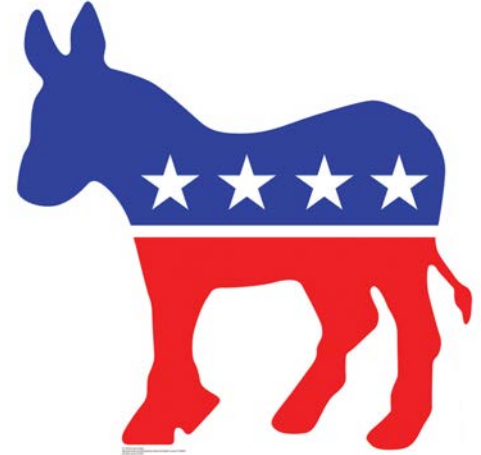


What Won't Happen:

- X Any legislative action to undermine the Affordable Care Act

What's On The Table For 2019?

- Shore up the Affordable Care Act (#1)
- Drug pricing (#2)
- “Medicare for All”? (#3)
- Drug importation
- E-cigarette regulations (Rep. Pallone)
- PBM reform
- 340B reform
- Lab-developed tests
- Cosmetics reform (Rep. Pallone)
- FDA oversight?



The Drug Pricing Story So Far....



President Trump @POTUS · Jan 31

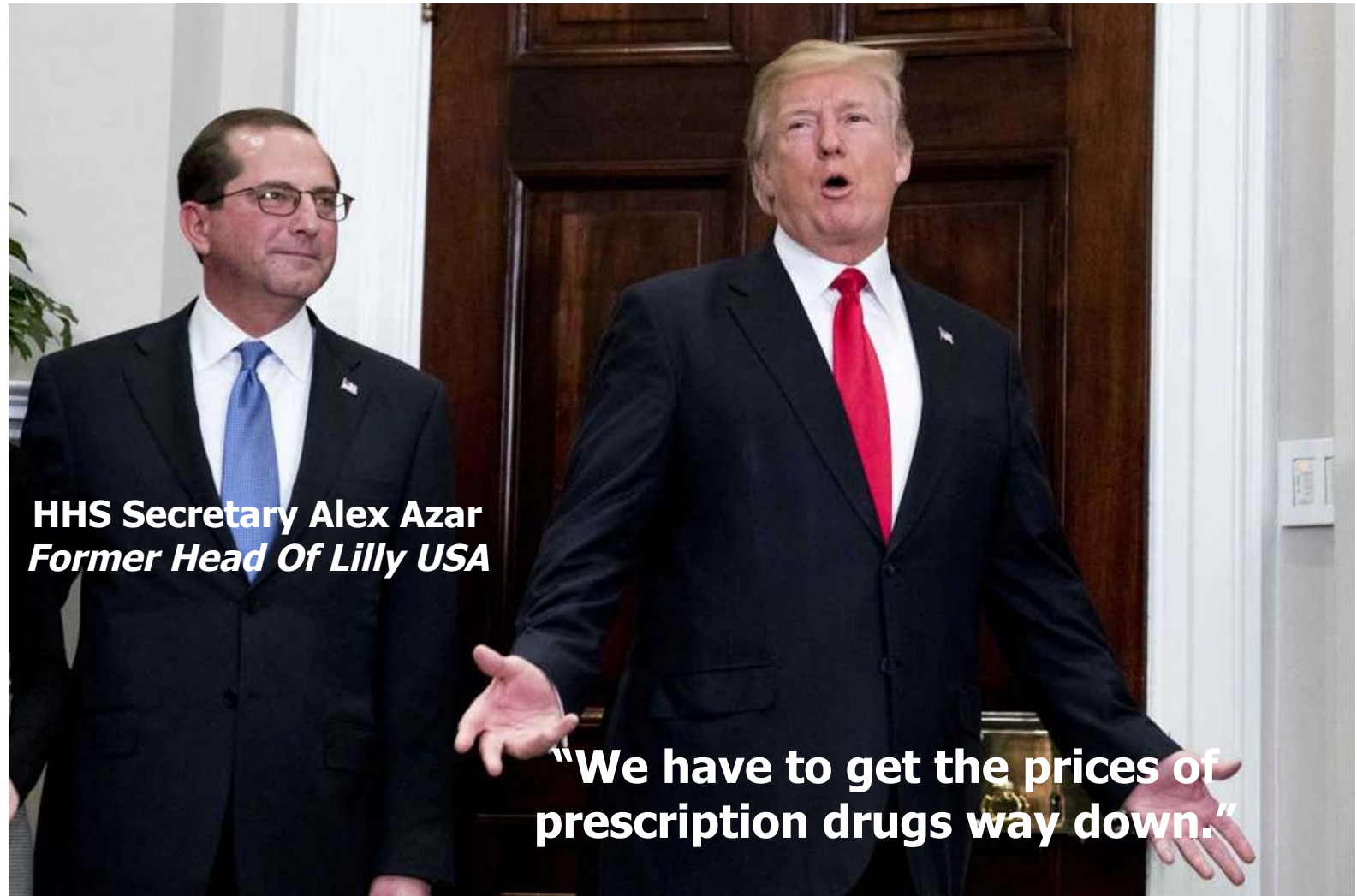
Today I met with pharmaceutical executives at the
[@WhiteHouse...facebook.com/DonaldTrump/po...](https://www.facebook.com/DonaldTrump/po...)



4.2K 5K 25K

"The pricing has been astronomical. You folks have done a very great job over the years but we have to get the prices down."

Azar Committed To Pricing Agenda



HHS Secretary Alex Azar
Former Head Of Lilly USA

**"We have to get the prices of
prescription drugs way down."**

Drug Pricing: A “Made for TV” Event



What *Isn't* In There?

X Medicare Price Negotiation

X Wholesale Parallel Trade (a.k.a., “Reimportation”)

X NIH “March In” On Patent Rights



A LOONNGGG To Do List

Incentives for Lower List Prices

Immediate Actions

- FDA evaluation of requiring manufacturers to include list prices in advertising
- Updating Medicare's drug-pricing dashboard to make price increases and generic competition more transparent

Further Opportunities

- Measures to restrict the use of rebates, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates
- Additional reforms to the rebating system
- Using incentives to discourage manufacturer price increases for drugs used in Part B and Part D
- Considering fiduciary status for Pharmacy Benefit Managers (PBMs)
- Reforms to the Medicaid Drug Rebate Program
- Reforms to the 340B drug discount program
- Considering changes to HHS regulations regarding drug copay discount cards

Lowering Out-of-Pocket Costs

Immediate Actions

- Prohibiting Part D contracts from preventing pharmacists telling patients when they could pay less out-of-pocket by not using insurance
- Improving the usefulness of the Part D Explanation of Benefits statement by including information about drug price increases and lower cost alternatives

Further Opportunities

- More measures to inform Medicare Parts B and D beneficiaries about lower-cost alternatives
- Providing better annual, or more frequent, information on costs to Part D beneficiaries

Increased Competition

Immediate Actions

- Steps to prevent manufacturer gaming of regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS)
- Measures to promote innovation and competition for biologics
- Developing proposals to stop Medicaid and Affordable Care Act programs from raising prices [in the private market](#)

Further Opportunities

- Considering how to encourage sharing of samples needed for generic drug development
- Additional efforts to promote the use of biosimilars

Better Negotiation

Immediate Actions

- Experimenting with value-based purchasing in federal programs
- Allowing more substitution in Medicare Part D to address price increases for single-source generics
- Reforming Medicare Part D to give plan sponsors significantly more power when negotiating with manufacturers

- Sending a report to the President on whether lower prices on some Medicare Part B drugs could be negotiated for by Part D plans
- Leveraging the Competitive Acquisition Program in Part B.
- Working across the Administration to assess the problem of foreign free-riding

Further Opportunities

- Considering further use of value-based purchasing in federal programs, including indication-based pricing and long-term financing
- Removing government impediments to value-based purchasing by private payers
- Requiring site neutrality in payment
- Evaluating the accuracy and usefulness of current national drug spending data

C. Lowering List Prices

In response to President Trump's call to action, HHS may:

- Call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.

“Think about all the time everybody spends watching drug company ads, and how much information companies are required to put in them. If we want to have a real market for drugs, why not have them disclose their prices in the ads, too?”

Consumers would have much more balanced information, and companies would have a very different set of incentives for setting their prices.

We're immediately going to look into having the FDA require this.”

-- Alex Azar, May 11, 2018

1) CMS Drug Price “Dashboard.”

- Resurrects Obama-era idea; publicize both bad actors and those adopting responsible behavior on Rx prices.

2) Reverse “gag rules” on pharmacies.

- CMS letter to PBMs telling them not enforce prohibitions on pharmacists presenting lower-cost options to patients.

3) “Name and shame” on REMS reforms.

- FDA to “publicly identify” manufacturers that “game” patent system by blocking access to generic samples.
- Has it led to any change in behavior? (Hint: No.)

4) DTC Price Disclosure Rule



The Legal Basis Is Dubious...
...As Is The Price Impact

But: Prompts PhRMA Policy
Change On Patient-Level
Pricing in New Disclosure
Policy

And: Has Bipartisan Support
(Everyone Seems To Hate DTC!)



Plus: Appeals To One
Key TV-Watching
Audience....

New DTC Disclosure:

“The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”



20732 Federal Register / Vol. 84, No. 91 / Friday, May 10, 2019 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS-4187-F]

RIN 0938-AT87

Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for the Medicare Parts A, B, C and D programs, as well as the Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC or list price) of that drug or biological product. This rule is intended to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize their out-of-pocket (OOP) costs and expenditures borne by Medicare and Medicaid, both of which are significant problems.

DATES: This rule is effective July 9, 2019.

FOR FURTHER INFORMATION CONTACT: Cheri Rice, (410) 786-6499.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Purpose and Statutory Basis

B. Summary of the Rule

C. Problems That This Rule Seeks To Address

D. How the Rule Addresses These Problems: Transparency in Drug Pricing Promotes Competition and Lowers Prices by Informing Beneficiaries

II. Summary of Analysis of, and Response to Public Comments

A. Secretary's Statutory Authority To Require List Prices in DTC Advertising for Manufacturers Whose Drugs Are Payable Under Titles XVIII or XIX of the Social Security Act

B. General Comments on Direct-to-Consumer Advertising

C. Use of Wholesale Acquisition Cost as List Price

D. First Amendment Considerations

E. Requirements in DTC Advertising Other Than WAC

F. Other Alternatives

G. Enforcement

III. Collection of Information Requirements

A. Wage Data

B. Information Collection Requirements Regarding Pricing Information (§ 403.1202)

IV. Regulatory Impact Analysis

A. Statement of Need

B. Overall Impact

C. Anticipated Effects

D. Alternatives Considered

E. Accounting Statement

I. Background

A. Purpose and Statutory Basis

Delivering better care at more transparent, lower prices is one way the Trump Administration is putting American patients first. The May 2018 Trump Administration blueprint to lower drug prices described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket (OOP) costs. The blueprint described four strategies: Boosting competition, enhancing negotiation, creating incentives for lower list prices, and reducing OOP spending.

The blueprint called for HHS to consider requiring the inclusion of list prices in direct-to-consumer (DTC) advertising. This final rule will improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs.

B. Summary of the Rule

In the October 18, 2018 *Federal Register* (83 FR 52789), we published a proposed rule titled “Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency” (hereinafter referred to as the “October 2018 proposed rule”). After consideration of the public comments received, we are finalizing this rule largely as proposed, with one modification to proposed § 403.1204(h) in response to comments, and other minor technical changes to improve clarity.

This final rule requires DTC television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. This final rule amends subchapter A, part 403, by adding a new subpart L.

New § 403.1202 requires that advertisements for certain prescription drugs or biological products on television (including broadcast, cable, streaming, and satellite) contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as WAC or the list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”

New § 403.1200 specifies that this requirement applies to any advertisement for a prescription drug or biological product distributed in the United States, for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act, except for a prescription drug or biological product that has a list price, as defined herein, of less than \$35 per month for a 30-day supply or typical course of treatment. The list price stated in the advertisement must be current, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. When the typical course of treatment varies based on the indication for which the drug or biological product is prescribed, the list price should represent the typical course of treatment associated with the primary indication addressed in the advertisement. To the extent permissible under current laws, manufacturers are permitted to include an up-to-date list price of a competitor's product, so long as they do so in a truthful, non-misleading way.

New § 403.1203 specifies that the required list price disclosure set forth in § 403.1202 must be conveyed in a legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

Finally, new § 403.1204 specifies that the Secretary will maintain a public list that would include the prescription drugs and biological products advertised in violation of these requirements. We anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising.

What Will Price Disclosure Look Like?



To learn more about cost and how Janssen can help, visit XARELTO.com



MOST* PATIENTS
PAY BETWEEN \$0 AND
\$47 PER MONTH.

MAINTENANCE
DOSE LIST PRICE
PER MONTH

\$448

*Actual costs may vary based on dosing, site of care, insurance coverage and your eligibility for support programs. Estimates from IQVIA™ claims data (11/2017–10/2018). All rights reserved.

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05/19 cp-69762v1

1-888-XARELTO

Option 1: Discontinue TV ads for some brands. (*Dependent on competition.*)

Option 2: Challenge the rule in court on First Amendment grounds. (*Legal underpinnings of the rule are weak.*)

Option 3: Not comply, and see what happens. (*Could be first step in a manufacturer who wants to challenge the rule in court.*)

What The Rule Does:

- Codify formulary tools previously given to Medicare Advantage and Part D plans via guidance
 - Prior authorization allowed for new patient starts only
- Point-of-prescribing price transparency system and explanation of benefits reports delayed until 2021

What The Rule Does *Not* Do:

- Exclude drugs in “protected classes” when prices rise faster than inflation
- Exclude new formulations of an existing single-source drug (“product hopping”)
- Eliminate any of the “protected classes”

1. Medicare Part D Rebate Rule (OIG)

- Eliminate “safe harbor” protecting rebates
- Could be killed in favor of a spending cap on OOP cost

2. Medicare Part B Reference Pricing Demo (IPI)

- Tight timeline before start of January 2020 plan year means unlikely to happen in the near term
- Not a popular option on Capitol Hill; could be de-prioritized or dropped altogether

Meanwhile On Capitol Hill....



What's Different This Time?

CEOs, not “outside experts,” are testifying (manufacturers, wholesalers, PBMs)

Range of hearing topics (drug supply chain, Medicare Parts B&D, generic drugs/biosimilars, insulin prices, Gilead's *Truvada* HIV pricing)



Senate Finance Committee
“Magnificent Seven” hearing
February 26

Key Takeaways

- A Lot of Bark, Little Bite
- Pharma Is Cool Under Pressure
- *Truvada, Humira*, Insulin Under Spotlight
- Steep Learning Curve for Congress
- The PBM “Middleman” Strategy is Working
- Bipartisan Calls to “Do Something”

HHS Administrative Steps

- DTC Drug Pricing Rule Implemented
 - Codification by Congress under Sens. Grassley/Durbin bill
- Medicaid Value-Based Contracts (Michigan, Oklahoma and Colorado)
- Medicaid “Netflix”-Like Subscriptions (Louisiana and Washington for hepatitis C)



Congressional Action

- H.R. 987, “Strengthening Health Care and Lowering Prescription Drug Costs Act” passes House floor May 16
 - CREATES (access to Rx samples for generic development)
 - “Pay for delay” (prohibit brand/generic deals to delay generics)
 - 180-day “parking” (discourage “parking” by a first generic applicant)
- CBO says \$5 billion in savings for three Rx pricing bills
- Will ACA protection add-ons doom the package?
- Orange/Purple Book upgrades unanimously pass House May 8
 - Facilitate approval of generics and biosimilars

- Medicare Part D rebate rule...OR
- ...Part D co-pay caps
- Medicare Part B international reference pricing demo (IPI)
- Average Sales Price inflation cap
- Targeted importation effort (is Florida a bellweather?)
- FTC study on drug pricing practices
- “Stop STALLING” Act (halting sham citizen petitions)
- Patent thickets (end abuse of patent system)
- SPIKE/FAIR Drug Pricing Acts (justify price hikes to HHS)
- “Sunshine for Samples Act”

Medicare for All: Is It Possible?



2020 Democrats Making It THE Issue To Run On

“Medicare for All Act” – Sen. Bernie Sanders and Rep. Pramila Jayapal

“Medicare X Choice Act” – Sens. Tim Kaine and Michael Bennet

“The Choice Act” – Rep. Jan Schakowski and Sen. Sheldon Whitehouse

“Medicare at 50” Act/“Medicare Buy-In” Act – Sen. Debbie Stabenow and Rep. Brian Higgins

“Choose Medicare Act” – Sen. Jeff Merkley and Rep. Cedric L. Richmond

“As long as I’m Majority Leader, socialist plans to give government total control over your life will never pass the Senate.”

-- Senate Majority Leader
Mitch McConnell



Republican Efforts to Repeal Obamacare End...

Last-ditch effort from Trump/Ryan (American Health Care Act) got a dismal score from the Congressional Budget Office

“Repeal and replace” was never inherently good for pharma



The Bad Parts

“Repeal And Replace”

With The Good Parts

...Or Have They?



Trump, GOP states ask appeals court to kill Obamacare

A decision to overturn President Barack Obama's signature health care law could leave millions uninsured.

What's At Risk

- Biosimilars pathway and 12-year exclusivity protection for biologics
- Contraception coverage mandate
- Medicare Part D donut hole discounts
- Medicaid expansion in 37 states plus D.C.
- Insurance exchanges
- Protections for pre-existing conditions
- CMMI and its new payment model demonstrations
- Medicaid rebates and 340B discount eligibility would return to pre-2010 levels
- Sunshine Act disclosure requirements

The State Of FDA



Scott Gottlieb Is Out

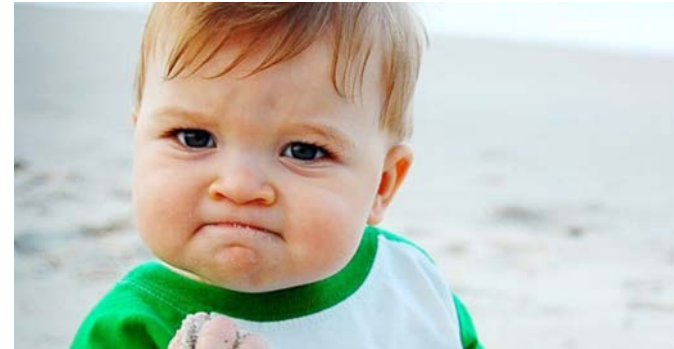


1. Put FDA Out In Front On Drug Pricing

- ✓ Can't set prices, but can promote innovation (REMS abuses, record generic/brand drug approvals, rebate effect on biosimilars).

2. Set New Policies On Opioids

- ✓ Comparative approval standard for new opioids.
- ✓ Study efficacy and safety of long-term use.
- ✓ Advance MAT options for opioid addiction.
- ✓ REMS for immediate-release opioids.
- ✓ Withdraw *Opana ER* from the market.



3. Tobacco Regulation/Teen Vaping

- ✓ Limit sale of flavored E-Cigs.

4. Retained (and Elevated) Legitimacy Of FDA

- ✓ Critical in succession planning.
- ✓ Sharpless is *not* a disruptor pick by the Trump White House.

A New (Acting) FDA Commissioner

Ned Sharpless, NCI Director Joined FDA effective April 8

“Let me dispel any misconceptions that the change in leadership reflects some desire of the President or the Secretary for the FDA to go in a different direction from the Gottlieb era.”

“I’m not acting as if this is a temporary or part-time job.”



Dr. Ned Sharpless ✓ @FDACommissioner · Apr 16

Today I had the opportunity to address the awesome FDA staff in person and share some of my first impressions on the job. I grabbed a quick pic to memorialize the event and my commitment to working together as one FDA [go.usa.gov/xmbDk](https://www.fda.gov/xmbDk)



16 30 242

- **Oncologist Automatically Inherits Two FDA Priorities...**
 - Ongoing efforts to streamline oncology clinical trials.
 - Gottlieb's anti-vaping bully pulpit.
- **...But It Begs the Question: Who is FDA's Top Oncologist?**
 - Sharpless-Pazdur relationship will be one to watch.
- **Sharpless' Biggest Challenges In Near Term**
 - Maintain FDA's reputation as active, anticipatory public health agency.
 - Prevent a ripple effect of resignations among senior career staff.
 - CDER's Woodcock retirement would be enormous loss to FDA.
 - Get to know *all* of FDA: "The FDA really has a huge portfolio!"
- **Senate Confirmation To Come: "Acting" Status Has Its Limits**
 - The sooner, the better for Sharpless and FDA – but Senate confirmation hearings may not be a priority.

- ✓ **Address Opioid Epidemic**
 - ✓ Implement opioid short duration of use packaging (blister packs).
 - ✓ Policies to encourage development of non-opioid alternatives.
 - ✓ OTC naloxone? (First Rx generic approved April 19.)
- ✓ **Communicate Safety of Vaccines Amid Measles Outbreaks**
- ✓ **Rethinking Oncology Clinical Trials**
- ✓ **Support Biosimilars/Interchangeability**
- ✓ **Office of New Drugs Restructuring**
- ✓ **Fill Vacancies In Key Leadership Positions**
- ✓ **Plus...**
 - ✓ Modernize Oversight of Dietary Supplements
 - ✓ Address CBD-Containing Foods and Supplements
 - ✓ Continue Crackdown on Illegitimate Stem Cell Clinics



Thank You!

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 **PREVISIONPOLICY**
HEALTH POLICY + BUSINESS FORECASTS

Drug Review Memorandum

11.4.2010

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Roche/Genentech's Avastin: FDA's Decision and CMS Implications

Summary: A decision by FDA on whether to pull a major indication in breast cancer for the oncology drug Avastin is approaching. In this note we lay out our thinking ahead of a likely Dec. 17 action date on the issue.

We continue to believe that FDA will rescind the first-line indication for metastatic breast cancer. That conclusion is based on the overwhelming vote coupled with the tone of FDA leadership in the oncology group at the meeting.

We also note that FDA's decision may not be the critical step in determining the impact of the re-evaluation of Avastin's role in breast cancer therapy. The Centers for Medicare & Medicaid Services (CMS) may also weigh in to review coverage of the indication, which would have a more dramatic impact on use of the therapy.

Finally, we include some background on precedents in the accelerated approval space that may be useful for considering potential outcomes.

Analysis: A decision by FDA on whether to pull a major indication in breast cancer for the oncology drug Avastin is approaching. Here is how we think FDA and CMS will respond to the changing situation.

FDA's Oncology Drugs Advisory Committee unanimously voted (13-0) on July 20 that the accelerated approval (AA) indication for first-line treatment of metastatic breast cancer should be removed from Roche/Genentech's Avastin (bevacizumab) label. Following the advisory committee, Roche/Genentech submitted additional data to FDA that triggered a three-month extension to the user fee deadline from September 17 to December 17.

We continue to believe that FDA will rescind the first-line indication for metastatic breast cancer. That conclusion is based on the overwhelming vote coupled with the tone of FDA leadership in the oncology group at the meeting.

The internal FDA analysis of two confirmatory studies for the breast cancer indication, AVADO and RIBBON1, found the trials did not support the improvement in progression-free survival (PFS) demonstrated in an earlier randomized study (E2100). The FDA concluded: "The magnitude of the improvement in PFS observed in these two studies failed to confirm the magnitude of PFS improvement observed in the E2100 trial, the basis for the accelerated approval."

If FDA revokes the breast cancer indication, there are several potential next steps, with CMS moving forward as the key decision-maker.

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