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Health Policy After the Midterms: What to Expect in 2019

Kate Rawson
Prevision Policy LLC
Coalition for Healthcare Communication
Post-Election Conference
November 27, 2018

Credit Where Credit Is Due

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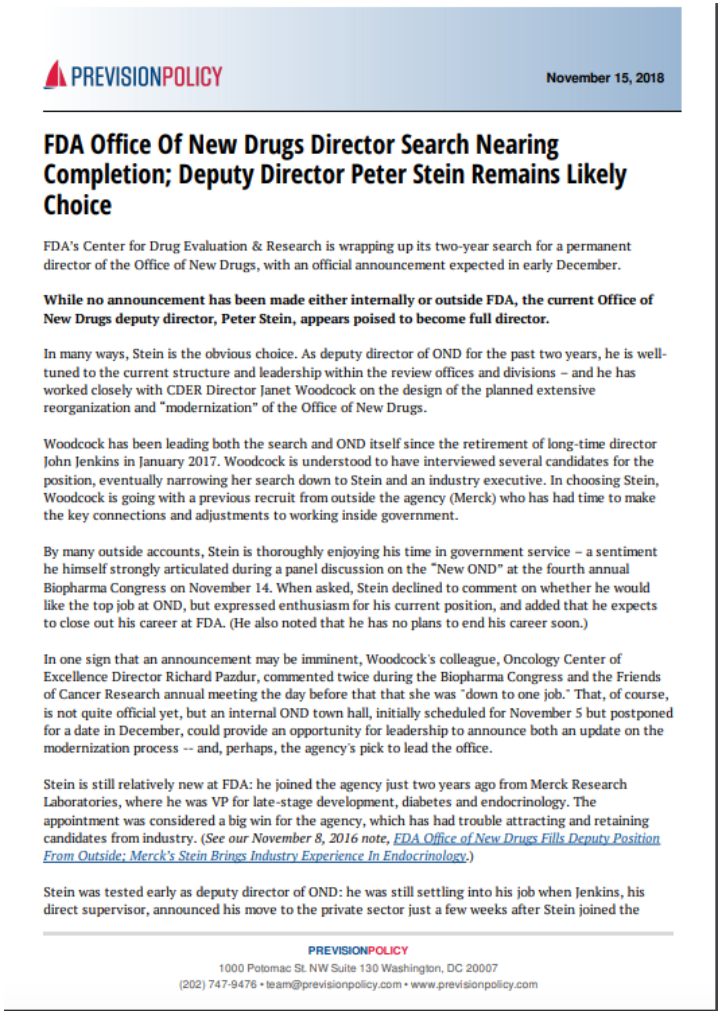
The Prevision Policy Team

Cole Werble
Michael McCaughan
Ramsey Baghdadi
Laura Helbling
Grace Moser



PREVISIONPOLICY 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

PREVISIONPOLICY
1000 Potomac St NW Suite 130 Washington, DC 20007
(202) 747-9476 • team@previsionpolicy.com • www.previsionpolicy.com

Topics for Discussion

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Midterms Deliver Divided Government

- Changes at the Committee Level
- Potential Lame Duck Legislation

Agency Watch: Who's Staying, Who's Out?

- FDA Commissioner Gottlieb Is Biggest Risk

Legislative Agenda for 2019

- Drug Pricing Is Health Policy Priority

What's Next For The Affordable Care Act

State of The FDA

- A "New" Office of New Drugs

Midterms Deliver Divided Government

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House Flips to Democrats, Hearings Will Follow

- Drug pricing, drug pricing drug pricing
- Protect ACA pre-existing conditions
- Opioids
- 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 Is a Big Winner In 2018

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Medicaid Expansion In Three GOP-Led States

- Ballot initiatives passed in Idaho, Utah and Nebraska

Gubernatorial Party Change Will Lead To Expansion

- Incoming Maine Gov. Janet Mills' (D) top priority

Democratic Gubernatorial Wins Could Lead To Future Expansion

- Wisconsin and Kansas had initially resisted expansion

Medicaid Expansion In 36 States Plus D.C.

- 14 states are still hold-outs

All in, 500K more beneficiaries could join Medicaid ranks

The New Faces Of House Leadership

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House Energy & Commerce Committee

- Rep. Frank Pallone (D-N.J.)
  - District is home to large pharma

E&C/Health Subcommittee

- Rep. Anna Eshoo (D.-Calif.) ✔
  - Major donations from pharma industry

- Rep. Diana DeGette (D-Colo.)
  - Co-author of 21st Century Cures; insulin prices

The New Faces Of House Leadership (2)

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House Oversight & Government Reform

- Rep. Elijah Cummings (D-M.D.)
  - Launched investigation in multiple sclerosis drug prices
  - Introduced legislation on importation and Medicare negotiation

House Ways & Means

- Rep. Richard Neal (D-Mass.)

Ways & Means/Health Subcommittee

- Rep. Lloyd Doggett (D-Texas)
  - Outspoken on lowering drug prices
- Rep. Mike Thompson (D-Calif.)

House Judiciary Committee

- Jerry Nadler (D-N.Y.)

The New Faces of Senate Leadership

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Senate Finance Committee

- Sen. Orrin Hatch Is Retiring
- Will Sen. Chuck Grassley (R-Iowa) Step In?
  - Bipartisan tendencies on drug pricing
  - Architect of Medicare Part D…
  - …but also teamed up with Sen. Ron Wyden on drug pricing/*Sovaldi* investigation
  - Sens. Cassidy and Burr next on pricing?

Senate Judiciary Committee

- Sen. Lindsey Graham (R-S.C.)

Looking Back: Health Care in 2018

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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 on the Affordable Care Act

Lame Duck Prospects

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What is Likely to Happen:

- ✓ Labeling bill – in honor of retiring Sen. Orrin Hatch
- ✓ Permanent repeal of ACA's 2.3% tax on devices. A third extension of the device tax moratorium is more likely.

What Could Happen:

- ➢ CREATES Act (access to generic Rx samples)
- ➢ Extend "no interference" state cannabis provision
- ➢ OTC user fees/monogram reform

What Probably Won't Happen:

X Orphan Drug Act amendment

X "Technical fix" to the donut hole discount paid by pharma companies (unless traded for CREATES Act)

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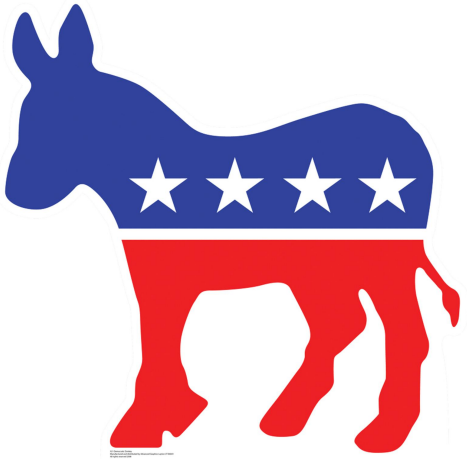
What's On The Table?

- 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)
- Opioid hearings – this time with drug manufacturers
- FDA oversight?



Trump's (New) Health Care Team

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HHS Secretary #1
Tom Price

HHS Secretary #2
Alex Azar
Former Lilly US CEO

CMS Administrator
Seema Verma

"Healthy Indiana" Author
Model For GOP Medicaid Expansion
Senate confirmed March 13

FDA Commissioner
Scott Gottlieb

Physician, Cancer Survivor
Former FDA, CMS Official
God-Like
Senate confirmed May 9

First Trump appointee at FDA: Anna Abram/point person on user fees

Alex Azar's Priorities for HHS

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- ✓ Lower drug prices.
- ✓ Address the opioid epidemic.
- ✓ Address the cost/availability of insurance – especially in the individual market.
- ✓ Value-based transformation of the health care system.

Azar's HHS: A Team Of Insiders

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Operations

Deputy Secretary Eric Hargan

Drug pricing

RIP: Senior Advisor Dan Best

CVSHealth

Pfizer

Health insurance

Office of Health Reform Senior Advisor Jim Parker

Anthem

MDwise

Opioids/mental health

Secretary for Mental Health and Opioid Policy Senior Advisor Brett Giroir,

veracyte

Agency Watch: Are Departures Coming?

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FDA Commissioner Scott Gottlieb Is Biggest Risk

Although there is no indication he will leave (yet)

CMS Administrator Verma Stays Under The Radar

Lower risk to industry if she does choose to depart

HHS Secretary Azar's Position Seems Secure

Unless He Moves To DoJ?

Already One Loss At HHS

Senior Advisor and Drug Pricing Lead Dan Best

ASPE Health Policy Deputy John O'Brien

Well-positioned to take over drug pricing lead

OMB Director Of Health Programs Joe Grogan

Near-term departure likely

The Drug Pricing Story So Far….

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

Drug Pricing: A “Made for TV” Event

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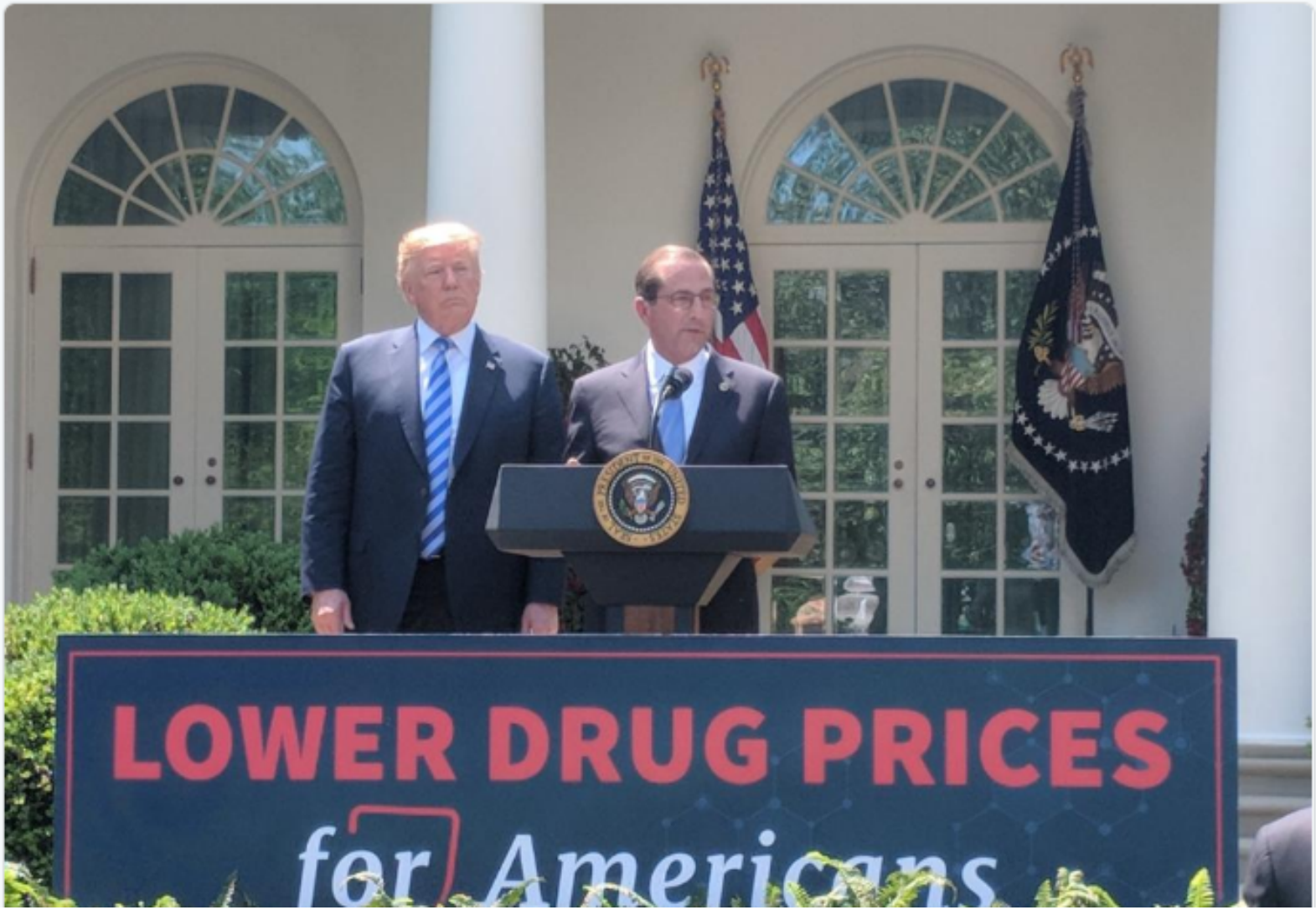

Immediate Changes Under "Blueprint"

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CMS Drug Price "Dashboard."

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

Reverse "gag rules" on pharmacies.

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

"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?

Medicare Advantage Step Therapy Under Part B

- Start in 2019; potential $2.4 bil. in annual savings.

DTC Proposal: All Bark, Little Bite?

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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

Surprise? DTC Price Disclosure

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- HHS would require disclosure of a drug's list price in DTC advertisements under October 15 proposed rule
  - 30-day supply or "typical course of treatment"
  - Unclear enforcement mechanism: "public list" of offenders, private lawsuits under Lanham Act
- PhRMA same-day announcement to update the industry's Code of Conduct
  - Timing suggests more coordination than confrontation, but Azar still blasted industry in announcing proposed rule
- *What's likely to have a bigger impact on DTC advertising?*
  - FDA "major statement" regulation slated to be finalized before July 2019, under HHS regulatory agenda

Medicare Part B "International Price Index"

- Proposed demonstration project to apply international reference pricing to Medicare Part B benchmarked to EU prices
  - ANPRM (and not a proposed rule) means long runway.
  - Early criticism is muted compared to Obama-era Part B demo, but expect the noise to grow.
- Five products most at risk:
  - Genentech's *Rituxan (*$1.06 billion)
  - Amgen's *Neulasta* ($946 mil.)
  - Regeneron/Sanofi's *Eylea* ($892 mil.)
  - Genentech's *Lucentis* ($852 mil.)
  - Amgen's denosumab brands *Xgeva/Prolia* ($850 mil.)
- *Question of Intent: Bring Industry to the Table…Or a Serious Proposal?*

Much More To Come On Drug Pricing

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- Medicare Part D: Changes to six protected classes?
  - Proposed rule in 2019, CMS says
- Indication-based pricing under Part D to start in 2020
- Removal of "safe harbor" protection for Part D drug rebates?
  - Pending Inspector General proposal
- Medicare B to D switch?
- Value-based payment models promised
- CMS will continue to issue state Medicaid waivers
  - Oklahoma, Michigan approved for value-based contracts

If all else fails…evoke NIH "march-in" rights?

Potential Price Disruptor?

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Subscription Purchase Model

- ✓ Louisiana Medicaid considering framework for **hepatitis C**
  - ✓ Collaboration with Gilead
  - ✓ Would require federal approval
  - ✓ Approximate start date of July 2019
  - ✓ Applicable to other diseases?

- ✓ FDA's Scott Gottlieb suggests potential approach for new, higher-priced **anti-infectives** by hospitals
  - ✓ Signal that FDA has maxed out regulatory reform on anti-infectives; next steps must come from payors

Beware the Bully Pulpit…

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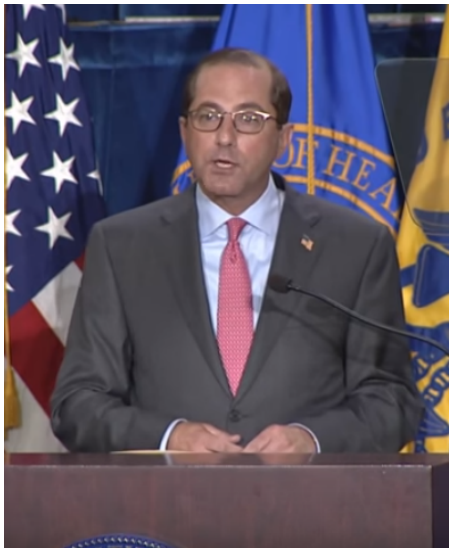
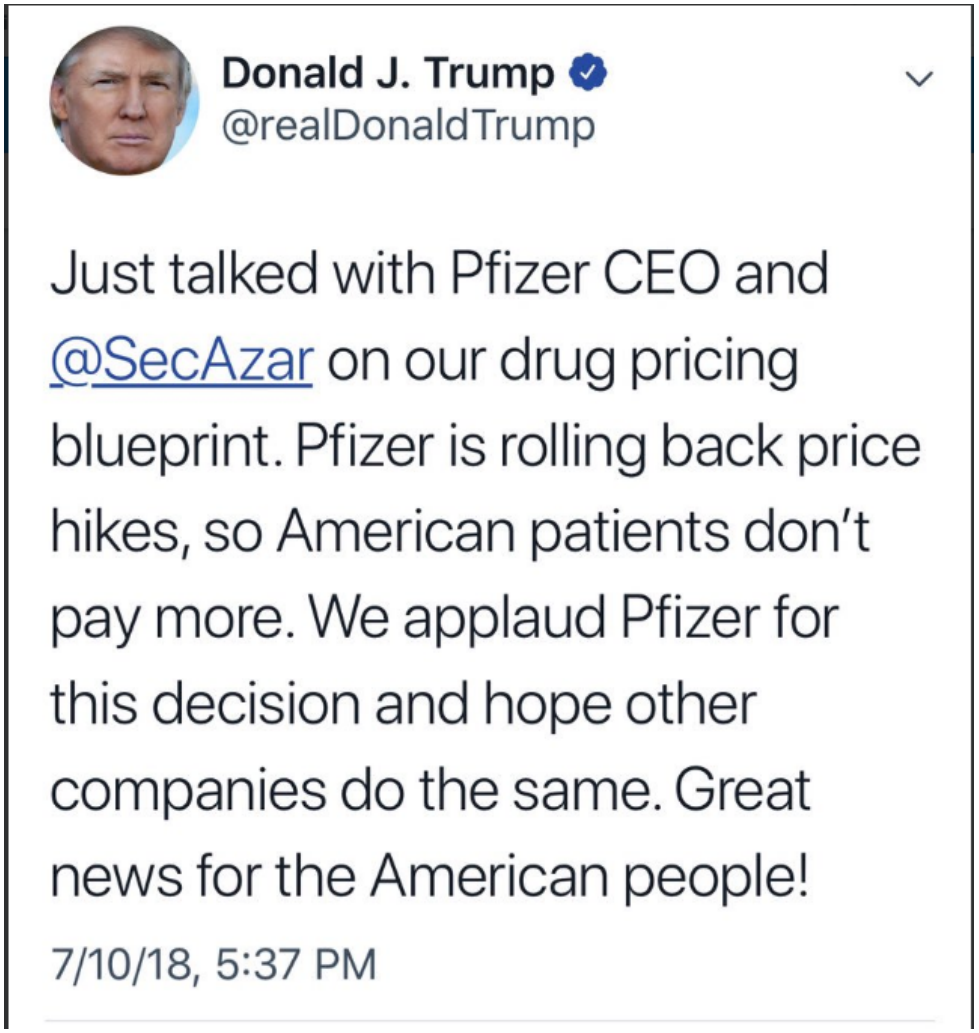


"I expect the President will be interested in hearing which companies lowered their prices and took other actions to support the changes we want to make."

Tough(er) talk from HHS Secretary Alex Azar

May 14, 2018



…But Are There Limits?

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THE WALL STREET JOURNAL.

BUSINESS

Pfizer to Raise Prices on 41 Drugs in January

The plans mean Pfizer would resume the practice of raising drug list prices after rolling back some increases under criticism from President Trump

The State Of FDA

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Scott Gottlieb's Extensive To-Do List

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- ✓ Address drug pricing through generic competition
- ✓ Curbing opioid abuse
- ✓ Accelerate complex generic drug approvals
- ✓ Encourage biosimilar uptake; ease path to interchangeability
- ✓ Accelerate drug development, including real-world evidence
- ✓ Digital health
- ✓ Continuous manufacturing processes
- ✓ Compounding policy
- ✓ Disease-specific industry guidance
- ✓ OTC user fees/monograph reform
- ✓ E-cigs/tobacco regulations
- ✓ Groom younger talent at FDA

Gottlieb's First-Year Successes

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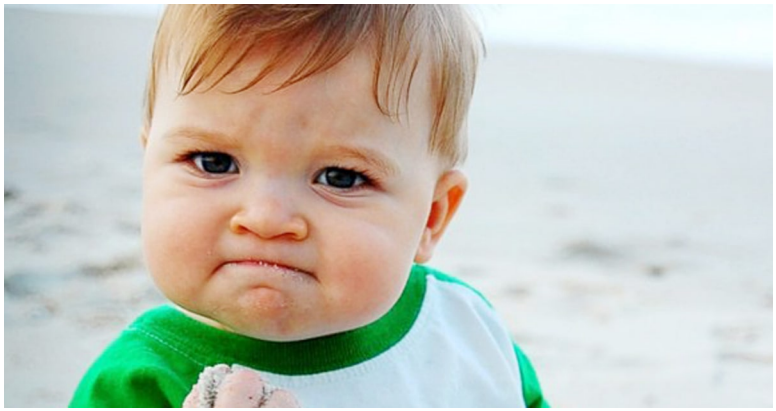
- ✓ Orphan drug SWAT team
- ✓ Disease-specific guidance rollout in bulleted format
- ✓ REMS for immediate-release opioids
- ✓ Withdraw *Opana ER* from the market
- ✓ Generic drug guidance development (especially complex drugs)
- ✓ Near-record novel drug approvals (46 in 2017)
- ✓ Record generic drug approvals in 2017 (1,027 full and tentative)
- ✓ RMAT implementation ("Cures")
- ✓ New drug review revamp



Gottlieb's Priorities For 2019

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- Rethinking Opioid Regulation
- Making A (Narrow) Drug Importation Policy Work
- E-Cigarette Regulation
- Any Food Safety Issues That Crop Up
- Implement Office of Commissioner Reorganization
- Find and Promote Younger Talent
- 21st Century Cures implementation
- PDUFA VI implementation
- "Right to Try"

Will He Stay – Or Will He Go?

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A “New” Office of New Drugs

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CDER Director Janet Woodcock

- ✓ More Review Divisions
- ✓ More Outward-Facing
- ✓ Common Review Memo
- ✓ Better Balanced Workload
- ✓ Smaller Review Teams
- ✓ Better Organized By Therapeutic Area

BUT: Does FDA Have The People To Lead Them?

FDA Brain Drain?

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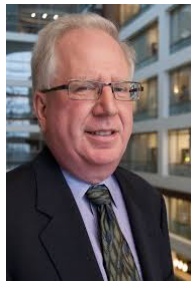
Robert Temple
CDER Deputy
Joined FDA 1972
46 years

Janet Woodcock
CDER Director
Joined FDA 1986
32 years

Doug Throckmorton
CDER Deputy
Joined FDA 1997
21 years

Richard Pazdur
OCE/OHOP Director
Joined FDA 1999
19 years



Tom Abrams
OPDP Director
Joined FDA 1993
25 years

RETIRED

John Jenkins
Office of New Drugs Director
Joined FDA 1992
25 years

Gerald Dal Pan
Office of Surveillance & Epidemiology
Joined FDA 2000
18 years

FDA Brain Drain?

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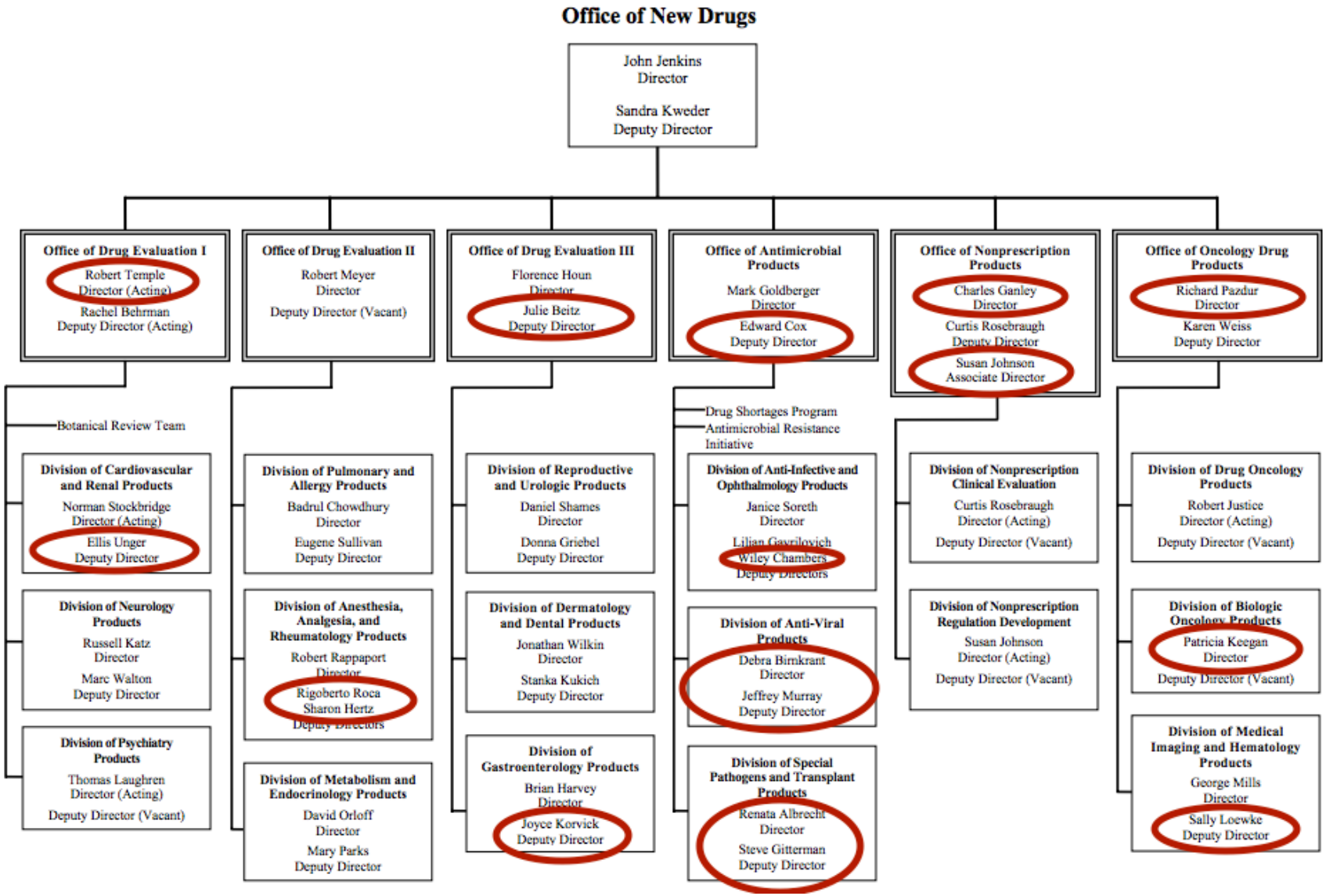

Thank You!

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Kate Rawson

Prevision Policy LLC

1000 Potomac Street NW

Suite 130

Washington DC 20007

202-297-6420

kate@previsionpolicy.com

@Kate_Rawson

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Drug Review Memorandum

11.4.2010

Ramsey Baghdadi 202·747·9476

Michael McCaughan 202·747·9477

Cole Werble 202·747·9478

Laura Helbling 202·747·9487

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.

PREVISIONPOLICY
1055 Thomas Jefferson St. NW
Suite 450A
Washington, DC 20007

PHONE (202) 747-9476
E-MAIL ramsey.baghdadi@PREVISIONPOLICY.com
WEBSITE HTTP://PREVISIONPOLICY.com