Health Policy After the Midterms: What to Expect in 2019

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Credit Where Credit Is Due

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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 CSER 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 (Stein) 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 she was “down to one job.” That, of course, is not quite official yet, but an internal OND town hall, initially scheduled for November 3 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, 2018 note, FDA Office of New Drugs Pick: Deputy Director Michael McCaughan Brings Industry Experience to 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
Topics for Discussion

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

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

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

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
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

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

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:
✗ Any legislative action on the Affordable Care Act
Lame Duck Prospects

**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:**

- CREATEES Act (access to generic Rx samples)
- Extend “no interference” state cannabis provision
- OTC user fees/monogram reform

**What Probably Won’t Happen:**

- Orphan Drug Act amendment
- “Technical fix” to the donut hole discount paid by pharma companies (unless traded for CREATEES Act)
Looking Ahead: After The Mid-Terms

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

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

✔ 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

Operations
Deputy Secretary
Eric Hargan

Drug pricing
RIP: Senior Advisor
Dan Best

Health insurance
Office of Health Reform
Senior Advisor
Jim Parker

Opioids/mental health
Secretary for Mental Health and Opioid Policy
Senior Advisor
Brett Giroir,
Agency Watch: Are Departures Coming?

**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 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
Immediate Changes Under “Blueprint”

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.
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
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
A Bigger Step?

**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

- 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…evolve NIH “march-in” rights?
Potential Price Disruptor?

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
“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

Just talked with Pfizer CEO and @SecAzar on our drug pricing blueprint. Pfizer is rolling back price hikes, so American patients don’t pay more. We applaud Pfizer for this decision and hope other companies do the same. Great news for the American people!

7/10/18, 5:37 PM
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.
Scott Gottlieb’s Extensive To-Do List

- 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

- 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

- 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?
A “New” Office of New Drugs

- 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?**

CDER Director Janet Woodcock
FDA Brain Drain?

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

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

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

RETIRED
Office of New Drugs

John Jenkins
Director

Sandra Kweder
Deputy Director

Office of Drug Evaluation I
Robert Temple
Director (Acting)

Rachel Behrman
Deputy Director (Acting)

Office of Drug Evaluation II
Robert Meyer
Director

Sandra Kweder
Deputy Director (Acting)

Office of Drug Evaluation III
Florence Houn
Director

Julie Beitz
Deputy Director

Office of Antimicrobial Products
Mark Goldberger
Director

Edward Cox
Deputy Director

Office of Nonprescription Products
Charles Ganley
Director

Susan Johnson
Associate Director

Office of Oncology Drug Products
Richard Paadur
Director

Karen Went
Deputy Director

Drug Shortages Program
Antimicrobial Resistance Initiative

Division of Cardiovascular and Renal Products
Norman Stockbridge
Director (Acting)

Ellis Ugger
Deputy Director

Division of Pulmonary and Allergy Products
Badul Chowdhury
Director

Eugene Sullivan
Deputy Director

Division of Reproductive and Urologic Products
Daniel Shames
Director

Donna Griebel
Deputy Director

Division of Anti-Infective and Ophthalmologic Products
Janice Soreth
Director

Liliana Guevarra
Deputy Director

Division of Gastroenterology Products
Brian Harvey
Director

Joyce Korvick
Deputy Director

Division of Anti-Viral Products
Debra Birkhan
Director

Jeffrey Murray
Deputy Director

Division of Special Pathogens and Transplant Products
Renata Albrecht
Director

Steve Gitterman
Deputy Director

Division of Biologic Oncology Products
Patricia Keegan
Director

Deputy Director (Acting)

Division of Medical Imaging and Hematology Products
George Mills
Director

Sally Loecke
Deputy Director

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