What’s Ahead For FDA? New Leadership, Challenges and Initiatives

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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 CDSR 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 longtime 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 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, 2016 note, FDA Office of New Drugs’ Deputy Director Positions From Outside: Merck’s Step Helps Industry Experience in Endocrinology.)

Stein was tasked 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

- New President, New Priorities
- Who Will Run FDA?
- State Of CDER Under Cavazzoni
- CBER’s Urgent Need To Staff Up
- Lessons Learned From COVID-19
- What’s In The UFAs?
- Biden’s Budget Priorities for FDA
Biden’s Health Care Team...So Far

HHS Secretary
Xavier Becerra
Senate confirmed March 18

HHS Deputy Secretary for Operations
Andrea Palm
Senate confirmed May 11

COVID Response
Chief Science Officer
David Kessler

CMS Administrator
Chiquita Brooks-LaSure
Senate confirmed May 25

FDA Commissioner
????
Janet Woodcock is Acting Commissioner
COVID-19 Response Continues To Be Job One

- Three vaccines authorized; full BLAs this summer/fall
- Closing of EUA window for vaccines demonstrates progress
- Vaccine booster planning is already underway
- Inter-agency effort to combat vaccine hesitancy (with CDC, NIH)
- Greater focus on COVID-19 therapeutics coming
FDA’s COVID Response: By The Numbers

- 3 authorized vaccines
- 610+ drug development programs in planning stages
- 450+ trials reviewed
- 10 treatments authorized for emergency use
- 1 COVID-19 approved treatment (remdesivir)
- 400+ Emergency Use Authorizations covering nearly 800 medical products: tests, sample collection devices, personal protective equipment and ventilators.

**Plus all the “regular” work within the Centers**
New President, New Priorities

**ARPA-H Is Biden Health Care Priority**
- Highlight of “skinny budget” proposal; $6.5 million
- NIH health funding entity to support health research projects for high-priority breakthroughs
- Little impact on FDA, but big changes possible in how government is pushing into development

**Supports IP Waiver For COVID Vaccines**
- Minimal immediate impact on manufacturers
- A one-off event, or a sign of things to come?

*Drug Pricing: Not an immediate priority*
The Next FDA Commissioner?

More Likely Picks

- David Kessler
- Luciana Borio

Dark Horses

- Janet Woodcock
- Rick Pazdur
- Josh Sharfstein
- Amy Abernethy
Round Two Of Potential Candidates

Florence Houn

Leana Wen

Katherine Luzuriaga

Michelle McMurry-Heath

Gayatri Rao
What Woodcock Brings To FDA

**Continuity During Crisis**
- 35 years of experience at FDA
- Deep understanding of needs

**Internal/External Support**
- Backing from staff, former Commissioners, some Hill
- Support from patient community

**Strong FDA Advocate On Hill**
- Adept at congressional testimony
Time To Nomination For FDA Commissioners By First-Term Presidents George W. Bush-Trump

- Mark McClellan (2002)
- Peggy Hamburg (2009)
- Scott Gottlieb (2017)
- Biden nominee/Woodcock as acting

Days To Nomination
The REAL Leadership Change Is At CDER

Fourth CDER director as of April 12; acting since May 2020

Woodcock’s hand-picked successor

Joined FDA from Pfizer in Feb 2018

Dr. Janet Woodcock

Pleased to announce the permanent appointment of Patrizia Cavazzoni, M.D., as @FDACDERDirector, a position she has been serving in for the past year and providing exceptional leadership during this critical and unprecedented time.
State Of CDER Under Cavazzoni

- Steer CDER out of pandemic work
- Finish user fee negotiations, including new OTC program
- “Health Equity” – in the form of generics and biosimilars (insulin)
- Continued focus on rare and neurodegenerative diseases
- Shore up supply chain reliability
- Immediate goal: winning “hearts and minds” of the CDER staff
But CBER Is Hot New Place To Work

“We have the the most important medical product of the decade, and gene therapies which are the wave of future medicine all in one center. It’s a pretty cool thing.

“Because of that, we've been able to attract some young talent.”
Repairing A Damaged Reputation

- Hydroxy EUA
- Oleandrin for COVID
- Plasma EUA
- "Deep state" at FDA
- "Rushing" a vaccine
FDA Is “Bruised, Not Broken”

**Morale Is An Ongoing Concern…**

- Staff has been going “non-stop” for 15 months
- 250 FTEs-worth of CDER work absorbed on COVID

**…But Hiring Is Booming At CDER During The Pandemic**

- 100+ net gains in employees in FY2020-2021
- Attrition at all-time low
- “Cures” authority now 20% of CDER staff
Lessons Learned From COVID-19

A “Fungible” Review Staff
- Re-assignments to busier areas helping ease strain
- FDA exploring “hybrid” work model going forward

Virtual Meetings Working (Relatively) Well
- Some sponsor meetings may be here to stay

FDA Is Continuing To Hire Through Pandemic
- Training new staff is complicated by virtual work environments
De-Centralized Trials The “New Normal”

- Patients prefer virtual visits
- More guidance from FDA coming

Investment Needed in Advanced Manufacturing

- Speedier ramp-up of vaccines for next pandemic

Virtual Inspections Could Replace Some Site Visits

- Flexibility after pandemic in cases where issues complicate or preclude in-person visits

Shortage Tracking Systems Are Here To Stay

- Monitoring system for COVID-related shortages to be retained and expanded
A Healthy Approval Environment

FDA Approvals of Novel Drugs/Biologics By Calendar Year

* 2021 data as of June 2
Inspections Will Be A Sticking Point
The Pandemic Impact

Human Drugs Establishment Inspections

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SOURCE: FDA budget justification, FY 2022  *estimated
The Pandemic Impact

48!! NDAs delayed by travel restrictions...

- Remote Inactive Evaluations where possible, but they can take longer than in-person visits; technology does not always make them possible.

- “Paper inspections” can be a black box for sponsors.

...including **six** mission-critical applications

SOURCE: FDA Resiliency Roadmap
Infected Clinical Trials?

- Remarkable flexibility to ensure patient safety
- Virtual visits to measure efficacy
- But sponsors need to document any deviations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020
Updated on January 27, 2021

For questions on clinical trial conduct during the COVID-19 pandemic, please email ClinicalTrialsconduct-COVID19@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)
Office of Good Clinical Practice (OGCP)
Heightened understanding of FDA’s public health mandate and complexity of the work it does

May (??) lead to more funding via appropriations

Potential downside: unrealistic expectations of what FDA can do – and how fast it can do it
Routine Maintenance for FDA

Congress Hauls in FDA Every 5 Years and Looks Under the Hood
PDUFA VII: 2022-2027

**Building On PDUFA VI**

- Model-Informed Drug Development
- Complex Innovative Trial Designs
- Patient-Focused Drug Development
- Real-World Evidence
- REMS Changes
- Sentinel Enhancements

**New User Fee Initiatives**

- Cell/gene therapy $$, guidance, meetings
- RMAT guidance, meetings, user fees
- Emerging IT
- Digital health
- Real-Time Review
Modest Increases For FDA

- $124 million for human drug operations (to $2.12 billion)
- $21 million increase for biologics (to $458 million)
- $18.8 million for inspections (FDA-wide)
- Much larger $76 million increase for data modernization efforts (to $83 million)

Drug Pricing: Punt to Congress
Thank You!

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