

Healthcare Policy In A Post-Trump World

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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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- Presidential Priorities In Biden White House
- Who Will Run HHS/FDA/CMS?
- Changing Faces On Key Senate Committees
- Drug Pricing: Is HR 3 Dead?
- The Future of the Affordable Care Act
- State of FDA
- Changing Face of OPDP
- PDUFA VII update



What We Won't Miss



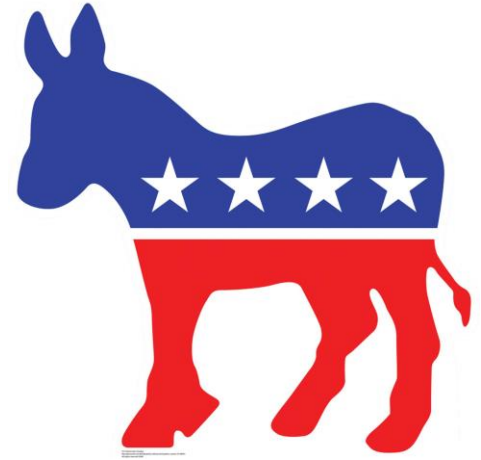
The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives! @SteveFDA

7:49 AM · Aug 22, 2020 · Twitter for iPhone

13.4K Retweets and comments 37.5K Likes



- COVID-19 Response/Pandemic Preparedness
- Economic Stimulus Plan
- “Build Back Better” infrastructure plan
- Green Initiatives (re-entering Paris Climate Agreement is #1)
- Shoring up the Affordable Care Act (if it survives)
- Drug pricing



COVID-19 Task Force Takes Shape



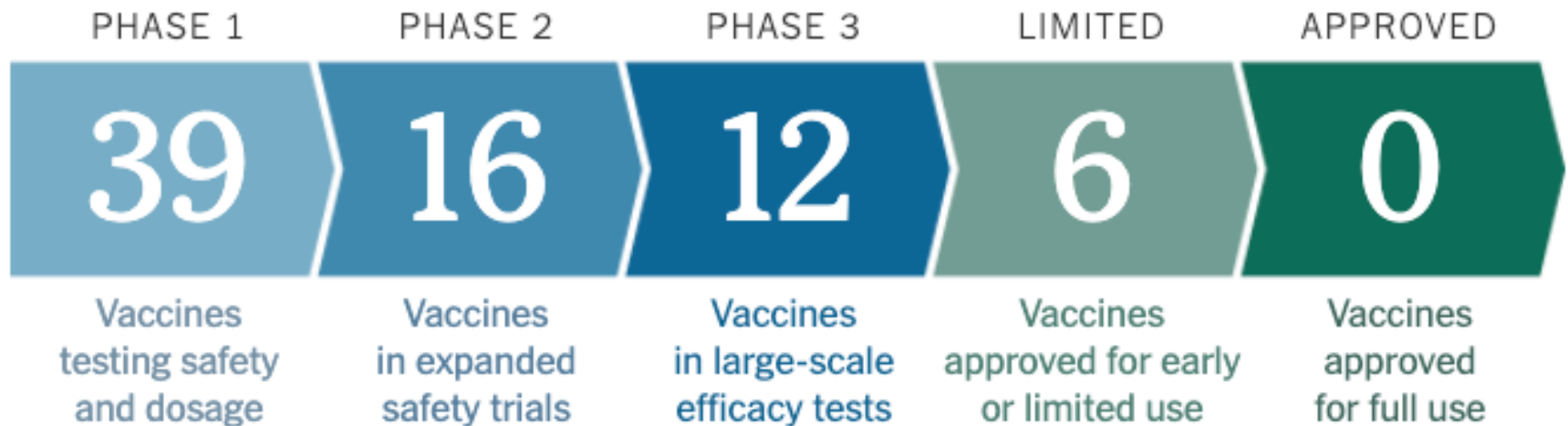


COVID-19

The Biden-Harris plan to beat COVID-19

- ✓ Give access to regular, reliable, and free testing
- ✓ \$25 billion in a vaccine manufacturing and distribution plan
- ✓ Establish a COVID-19 Racial and Ethnic Disparities Task Force
- ✓ Create the Nationwide Pandemic Dashboard with zip code search
- ✓ Build toward an American-sourced manufactured capability
- ✓ Implement nationwide mask mandate with governors and mayors
- ✓ Fix personal protective equipment problems for good.

Global COVID-19 Vaccine Tracker



Source: The New York Times
Data as of November 13



Steps to a Vaccine

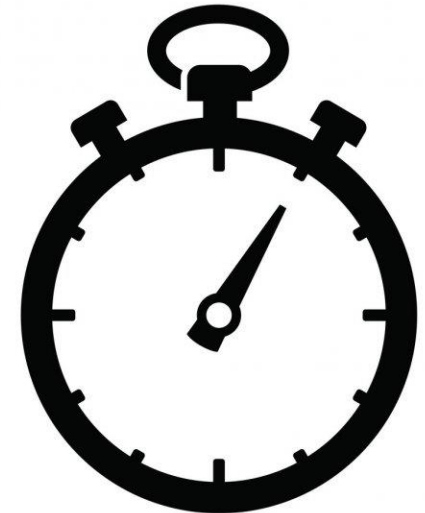
- ✓ Safety data
- ✓ Submit EUA to FDA
- ✓ Advisory committee
- ✓ “EUA-plus” standard
- ✓ ACIP sets guidelines
- ✓ Distribution rollout
- ✓ Full licensure to follow



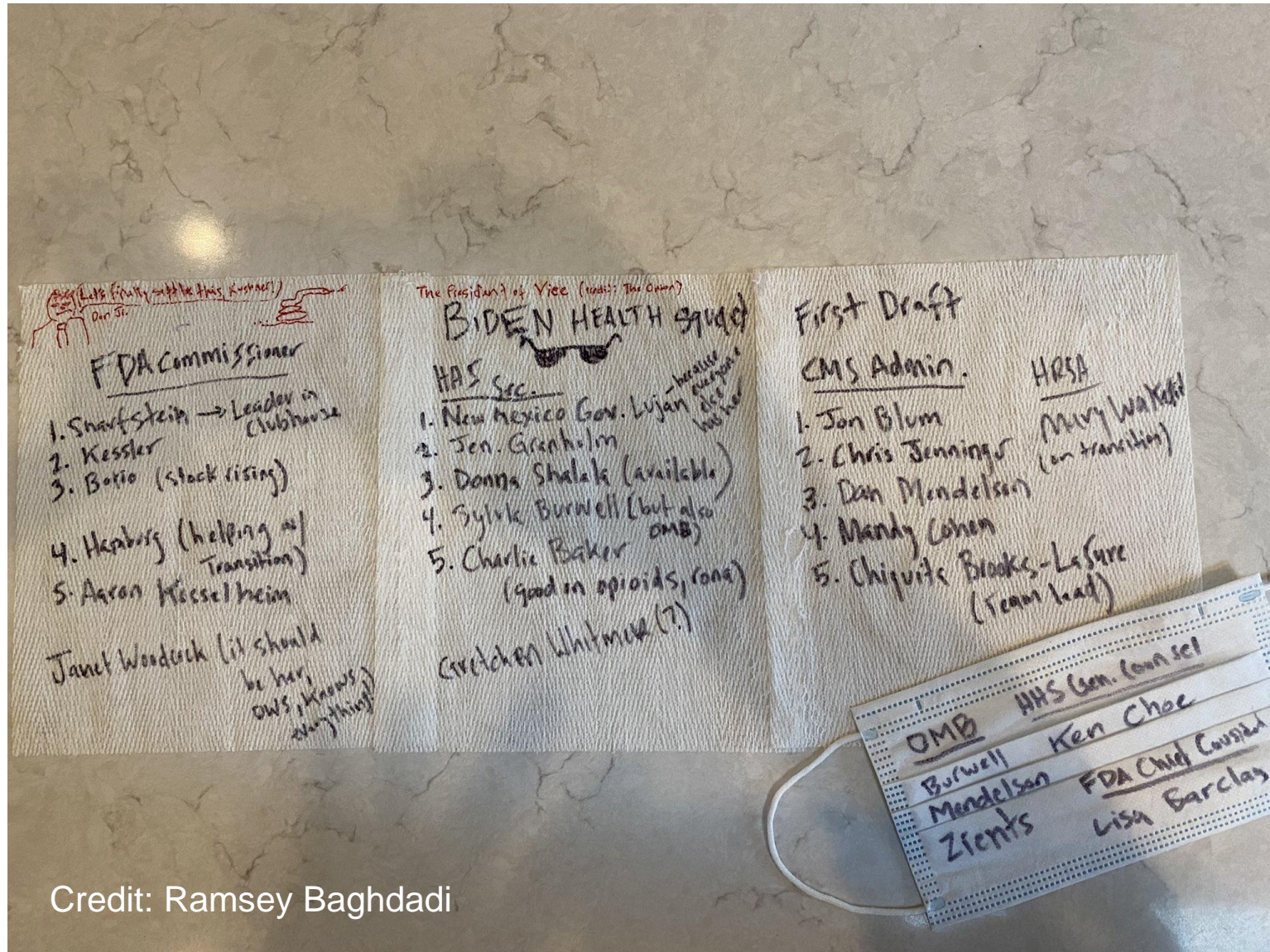
How Fast Is “Fast”?

Merck's antiretroviral *Crixivan* (indinavir): 42 days (six weeks) from application submission to approval in 1996.

GSK's *Fluarix* (influenza vaccine) needed just 99 days (14 weeks) from submission to approval in 2005.



Biden's Health Policy Squad



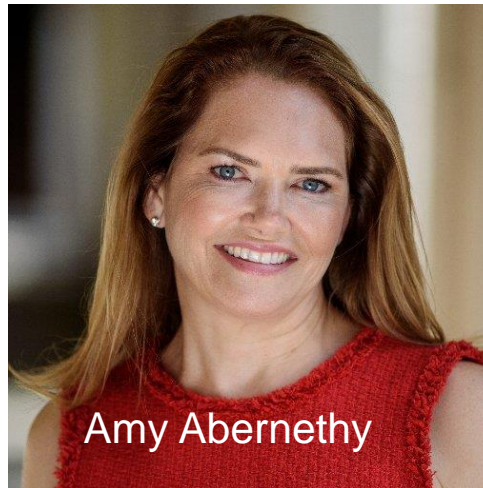
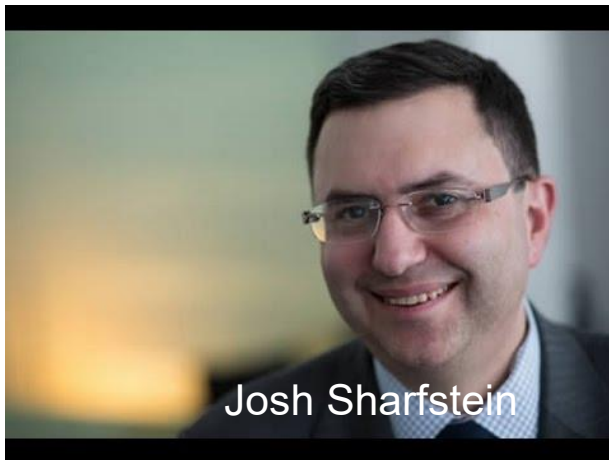
Credit: Ramsey Baghdadi

Who Will Lead HHS?

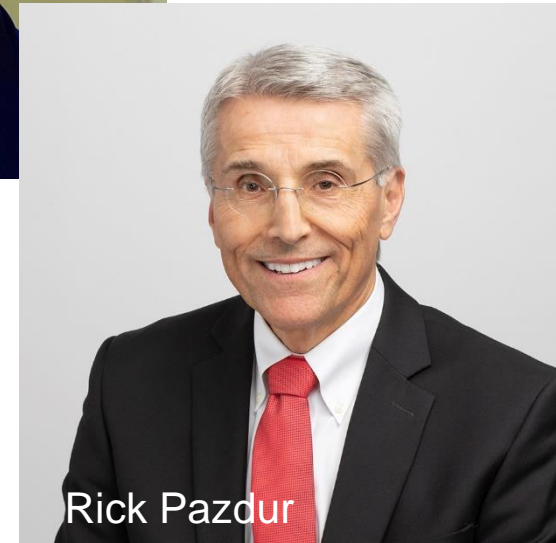
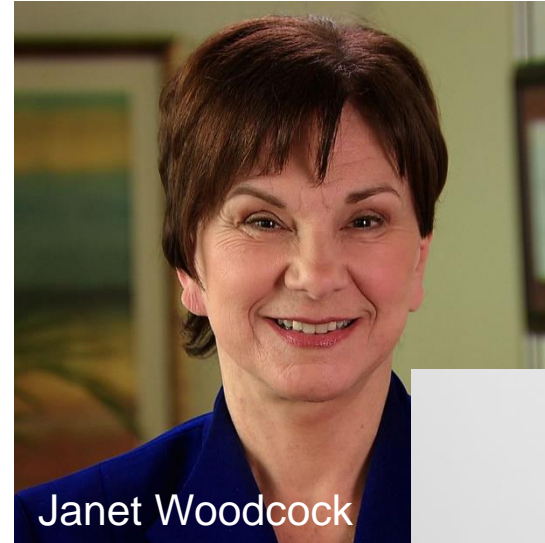


The Next FDA Commissioner?

More Likely Picks

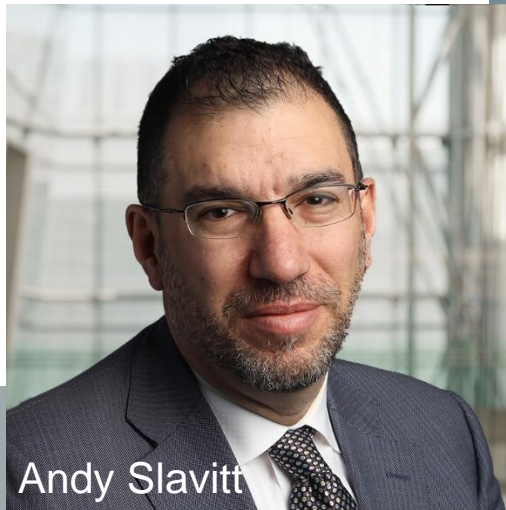


Dark Horses



The Next CMS Administrator?

Chris Jennings



Andy Slavitt



Dan Mendelson



Jon Blum



Mandy Cohen

Meanwhile On Capitol Hill....



Most Likely Scenario



- ✓ Democrats lose ground but maintain majority
- ✓ Nancy Pelosi expected to remain leader



- ✓ Republicans have edge with 50-48 split
- ✓ Georgia run-offs Jan. 5 will determine majority
- ✓ Best case for Democrats is 50-50; Harris would be tie-breaker

Senate HELP (Republican Control)



- Sen. Richard Burr (N.C.) is next in line to succeed a retiring Lamar Alexander as chair...
 - BUT: ongoing ethics investigation could complicate matters
- Sen. Rand Paul (KY) would be next in line
 - Worse-case scenario for pharma

Senate HELP (Democratic Control)



- Sen. Patty Murray (Wash.)
- Sen. Bernie Sanders would be next in line
 - Worse-case scenario for pharma

Senate Finance (Republican Control)



- Sen. Mike Crapo (Idaho) most likely to succeed Chuck Grassley (Iowa) as chair
 - Grassley moving to Judiciary
 - Bipartisan drug pricing bill less likely w/o Grassley

Senate Finance (Democratic Control)



- Sen. Ron Wyden (Ore.)
 - More aggressive on drug pricing
 - Worse-case scenario for pharma



State of the Affordable Care Act

2010: Congress passes Affordable Care Act

2012: Supreme Court upheld ACA, ruling 5-4 in *National Federation of Independent Business v. Sebelius* that individual mandate was constitutional, in that it amounted to a tax

2017: Congress eliminated the individual mandate

November 10, 2020: The high court heard oral arguments in *Texas v. California* over whether the ACA is unconstitutional without the individual mandate in place.

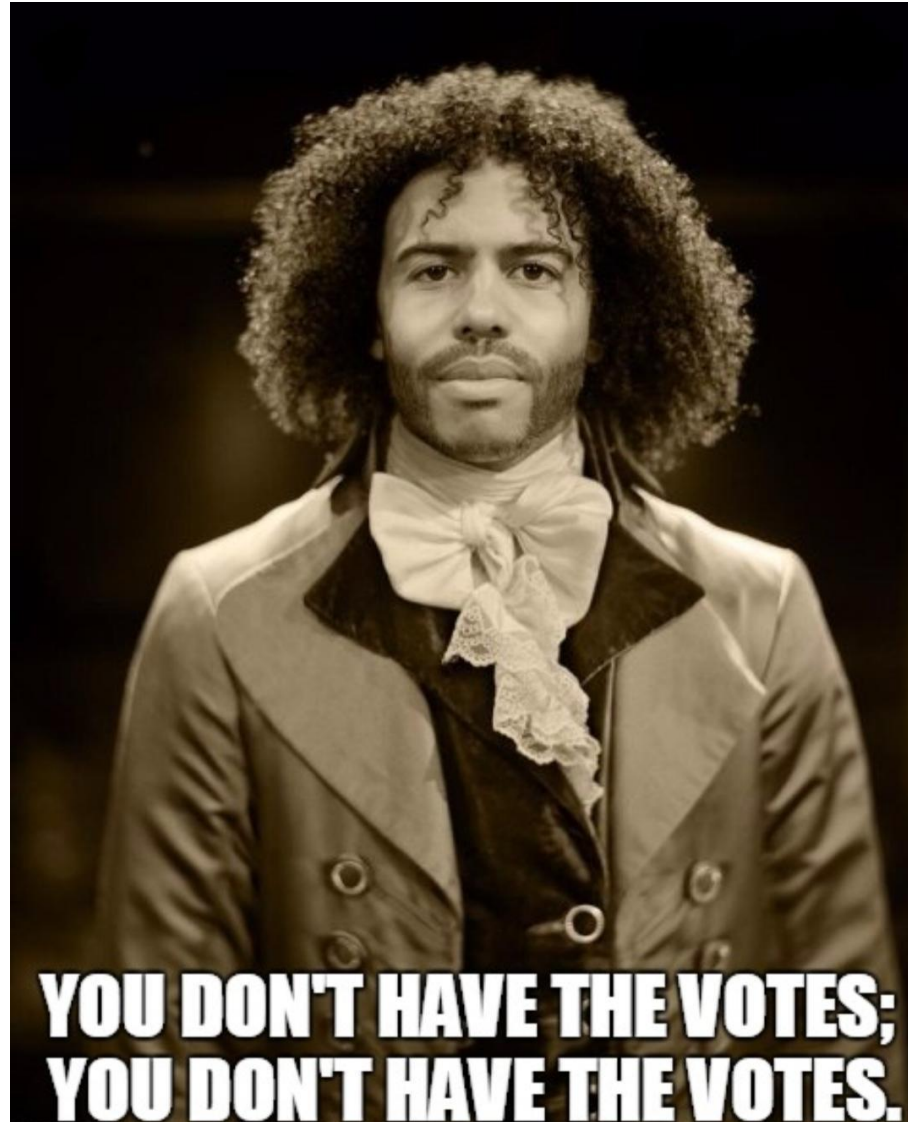
Early 2021: Ruling likely to uphold ACA



A Reminder of 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

ACA Expansion: Can It Happen?



The State Of FDA

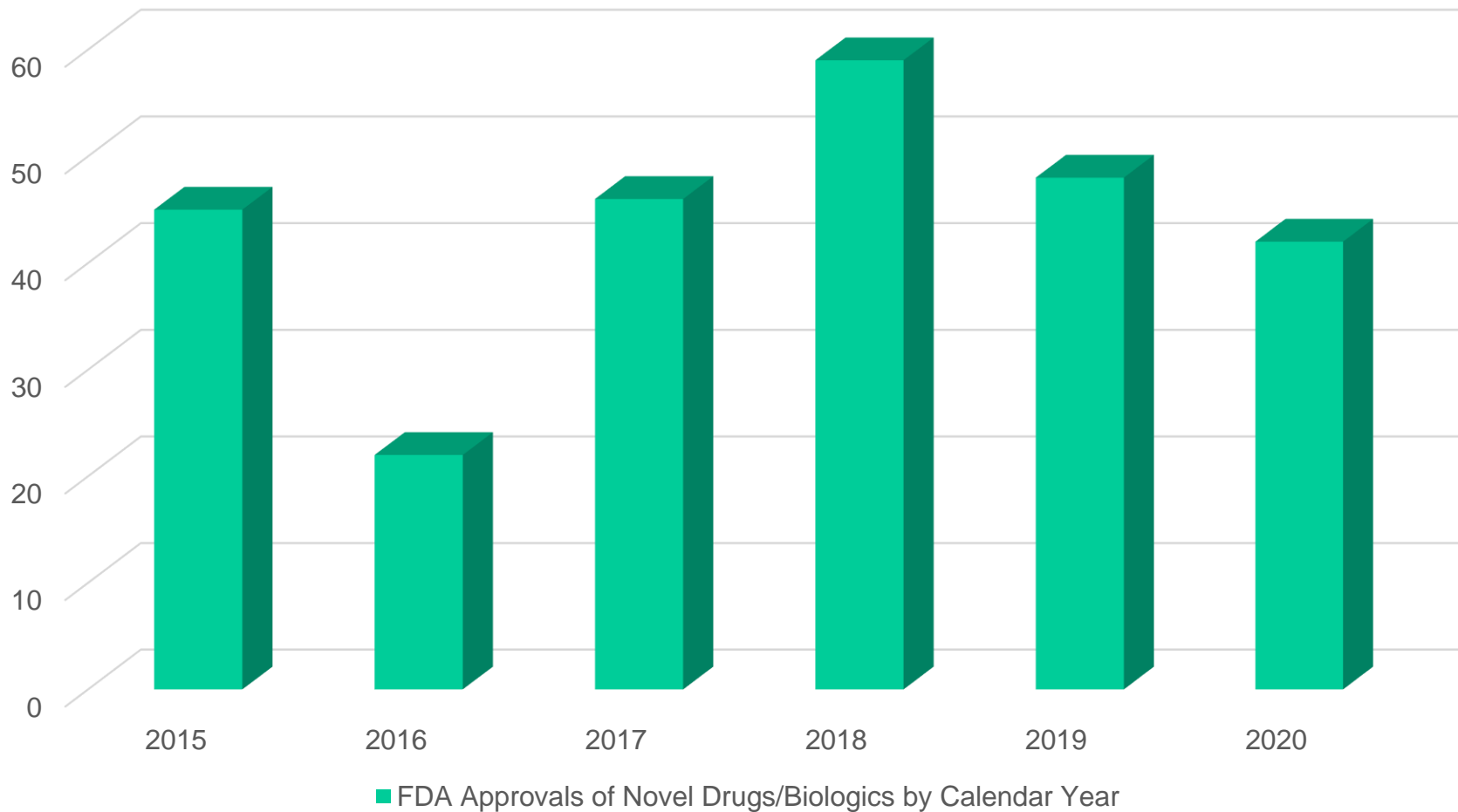


Repairing A Damaged Reputation



- **A “Fungible” Review Staff:** Re-assignments to busier areas are helping ease strain
- **Staff Morale Is Quite High:** Review teams see work as essential
- **Virtual Meetings Working Relatively Well:** And some may be here to stay
- **FDA Is Continuing To Hire:** Although training new staff is complicated by virtual work environments

FDA Approvals of Novel Drugs/Biologics by Calendar Year



*2020 data as of 11/12/2020



CDER Management: Old Hands, New Faces



Robert Temple
CDER Deputy
Joined FDA 1972
48 years



Janet Woodcock
CDER Director
Joined FDA 1986
34 years



Patrizia Cavazonni
Acting CDER
Director
Joined FDA 2018
2 years



Doug Throckmorton
CDER Deputy
Joined FDA 1997
23 years



Richard Pazdur
OCE/OHOP Director
Joined FDA 1999
21 years



Peter Stein
Office of New Drugs Director
Joined FDA 2016
4 years



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



Tom Abrams
OPDP Director
Joined FDA 1993
27 years

Catherine Gray is Acting Director

- Tom Abrams retired October 23
- Seamless transition expected



Changes Coming to Core Launch Review Process

- improve efficiencies;
- maximize use of FDA's resources;
- provide timely feedback to firms; and
- ensure prescription drug promotion is truthful, balanced, and accurately communicate

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.”



No More In-Person Speaker's Bureaus?



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



- No requirements imposed, in-person speaker's bureaus being discouraged
- Recent Corporate Integrity Agreements with Purdue, Novartis
- Opportunity to move away from in-person events given the social distancing restrictions required of pandemic
- **Red flags for OIG:** free drinks, overpaying for time, high-end venues, invite family members

Routine Maintenance for FDA



Congress Hauls in FDA Every 5 Years and Looks Under the Hood

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

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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