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Biden's Health Policy Priorities: Where We Are And What's To Come

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Credit Where Credit Is Due

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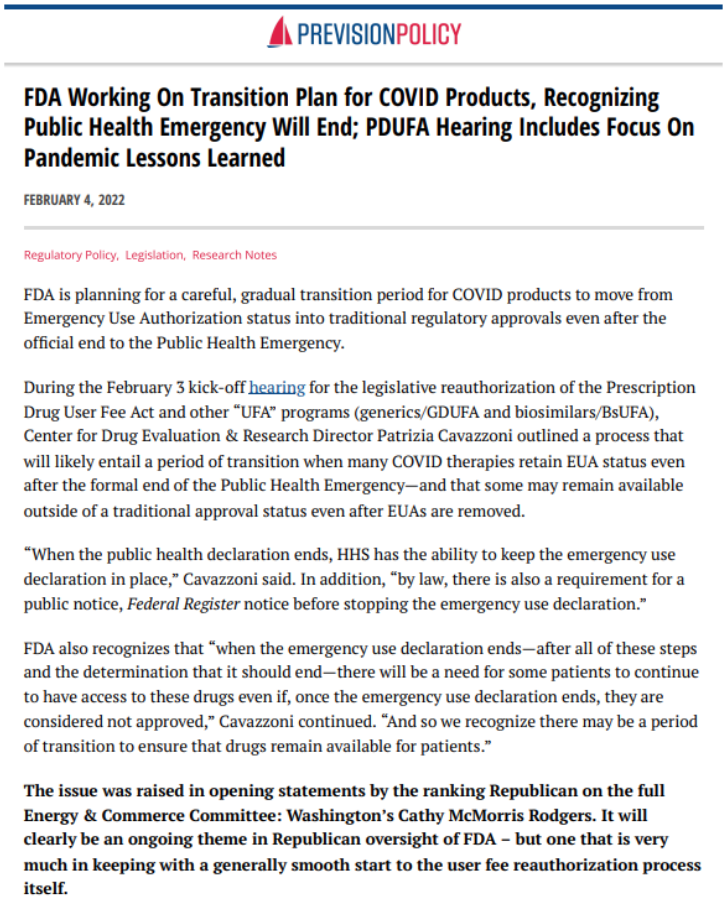

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FDA Working On Transition Plan for COVID Products, Recognizing Public Health Emergency Will End; PDUFA Hearing Includes Focus On Pandemic Lessons Learned

FEBRUARY 4, 2022

Regulatory Policy, Legislation, Research Notes

FDA is planning for a careful, gradual transition period for COVID products to move from Emergency Use Authorization status into traditional regulatory approvals even after the official end to the Public Health Emergency.

During the February 3 kick-off hearing for the legislative reauthorization of the Prescription Drug User Fee Act and other "UFA" programs (generics/GDUFA and biosimilars/BsUFA), Center for Drug Evaluation & Research Director Patrizia Cavazzoni outlined a process that will likely entail a period of transition when many COVID therapies retain EUA status even after the formal end of the Public Health Emergency—and that some may remain available outside of a traditional approval status even after EUAs are removed.

"When the public health declaration ends, HHS has the ability to keep the emergency use declaration in place," Cavazzoni said. In addition, "by law, there is also a requirement for a public notice, *Federal Register* notice before stopping the emergency use declaration."

FDA also recognizes that "when the emergency use declaration ends—after all of these steps and the determination that it should end—there will be a need for some patients to continue to have access to these drugs even if, once the emergency use declaration ends, they are considered not approved," Cavazzoni continued. "And so we recognize there may be a period of transition to ensure that drugs remain available for patients."

The issue was raised in opening statements by the ranking Republican on the full Energy & Commerce Committee: Washington's Cathy McMorris Rodgers. It will clearly be an ongoing theme in Republican oversight of FDA – but one that is very much in keeping with a generally smooth start to the user fee reauthorization process itself.

Topics for Discussion

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- New President, New Legislative Priorities
- COVID Communication: Missteps and Miscalculations
- PDUFA 7: What Could Hang On The User Fee Tree?
- Biden's Moonshot Relaunched
- A "Better" BBB? What's Possible On Drug Pricing?
- The Future of the ACA
- Looking Ahead: What's Possible Before The Midterms

Priorities For The Biden Administration

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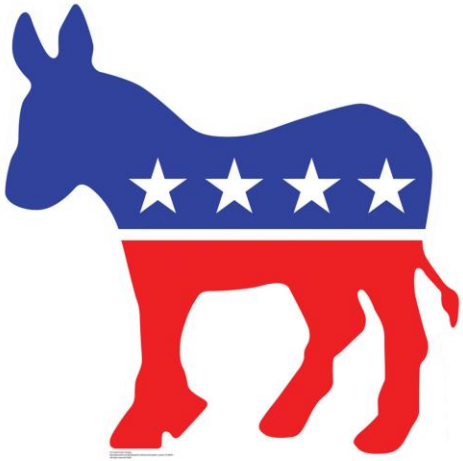
- COVID-19 Response/Pandemic Preparedness
- Economic Stimulus Plan
- “Build Back Better” infrastructure plan



- Green Initiatives (re-entering Paris Climate Agreement is #1)
- Shoring up the Affordable Care Act against potential Republican majorities
- Drug pricing

Biden's Health Care Team

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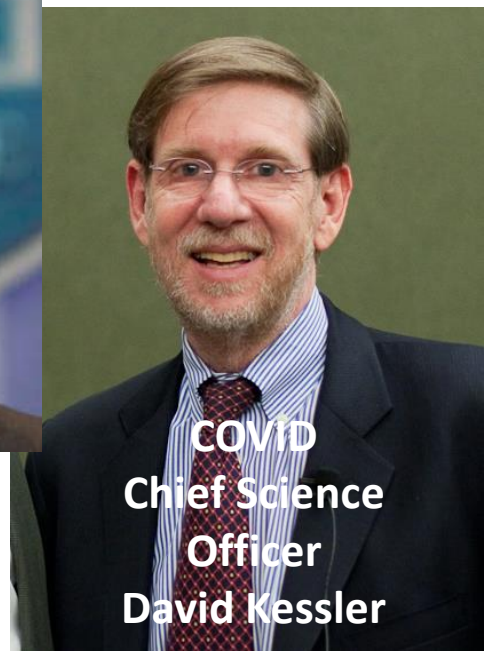

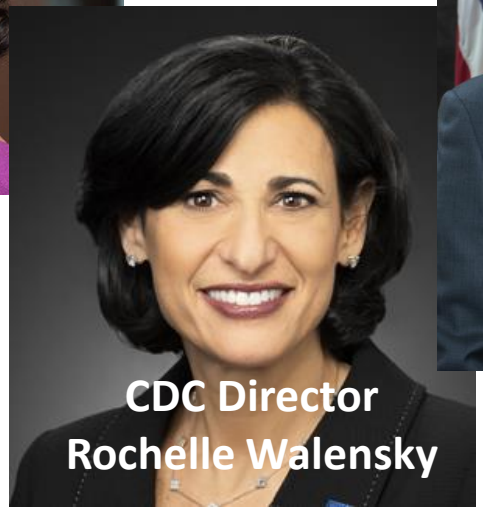

Biden's Promise: "Follow The Science"

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A Damaged Reputation

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Isolation and quarantine requirements

Mask mandates for vaccinated

Changing booster recommendations

Lack of COVID tests

CDC Director Rochelle Walensky

A Damaged Reputation

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For C.D.C.'s Walensky, a Steep Learning Curve on Messaging

Fauci and Walensky Can Start Being Candid

If health officials continue to distrust the public, the public will continue to distrust them.

Booster confusion takes hold as Biden announces expanded eligibility

The Biden administration has a COVID credibility crisis

Congress Piles On

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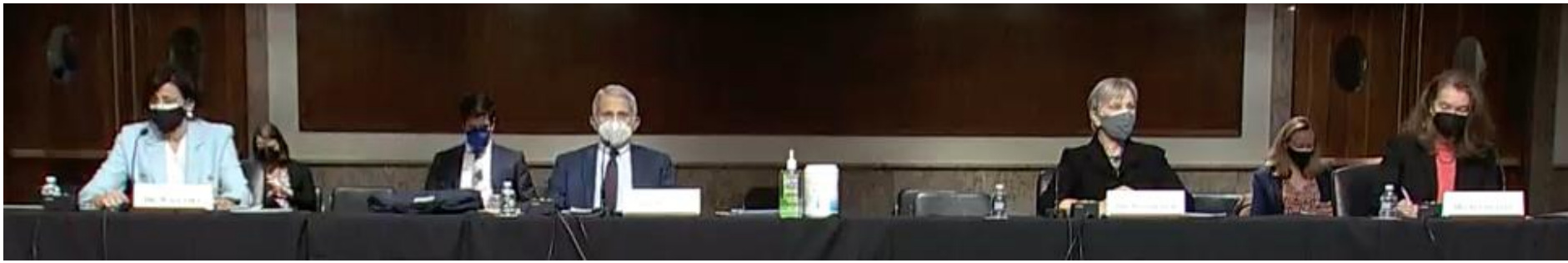

"You've lost the trust of the American people."

Sen. Richard Burr (R-N.C.)

Senate HELP hearing, January 11, 2022

Where Is Becerra?

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Where Is The Commissioner?

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F.D.A. Nominee Faces Steep Climb to Senate Confirmation

Dr. Robert Califf, a former agency commissioner, is encountering opposition over federal opioid and abortion policies and his industry ties.

Where Is The Commissioner?

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Scrambling to Find Democratic Votes…

- Concessions required from Warren (ethics pledge); Wyden (clean up of Accelerated Approval); Lujan (opioids) and Durbin (e-cigarettes)
- Three previous votes against Califf say they will not support him (Manchin, Markey, Blumenthal)
- Two more will vote against due to opioid crisis (Hassen and Sanders)

…While Republicans Face Pro-Life Pressure

- Just four Republicans have publicly backed his candidacy (Burr, Collins, Murkowski, Romney)

Senate vote expected February 15

What If Califf Isn’t Confirmed?

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Immediate Issues for Biden's FDA

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- COVID vaccine oversight, continued
  - Two approved BLAs for adults; Novavax files EUA
  - Under 5s next on deck – but delayed until April
  - Eventual transition out of EUAs
- Clean up Accelerated Approval's confirmatory study requirements
- Opioids redux
- Reduce inspections backlog (operations resumed February 7)
- Pass user fee authorizations (medical devices delayed)
- Reopen White Oak…and address WFH policies
- Establish policies to address "alternative paths to market"
- Rebuild FDA integrity post *Aduhelm*
- Vaping, food safety, cosmetics regulation…and everything else

What Does Aduhelm Say About FDA?

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Meanwhile On Capitol Hill….

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What Could Hang On PDUFA 7?

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Is "Cures 2.0" The Legislative Vehicle?

- Antimicrobial incentives (PASTEUR Act)
- Decentralized clinical trials **new**
- Real-world evidence in AA confirmatory trials
- Creation of two "intercenter institutes" (long-haul COVID and rare diseases)
- Ensure Medicare coverage of Breakthrough products

ARPA-H is centerpiece of "Cures 2.0" legislation

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ARPA-H Is Biden Health Care Priority

- Health funding entity to support research projects for high-priority "breakthroughs"
  - Under NIH – or separate HHS entity?
- Initial focus on cancer, diabetes and Alzheimer's for "transformational innovation"
- Modeled after BARDA (HHS) and DARPA (DoD) investments in COVID vaccines/therapeutics
  - "Fail fast; fail early" mentality
- Outsized attention: $6.5 billion versus $51 billion NIH budget

Biden’s Cancer Moonshoot Relaunched

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What's Possible For Drug Pricing?

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HR 3 Price "Negotiation" Bills

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House-Passed (2019)

- International reference pricing model based on six countries
- Manufacturers to accept price no higher than median, but no lower than lowest country price
- OR pay 95% excise tax
- Drugs/year to be "negotiated" started at 25; ramp to 50
- CBO savings: $492 billion

Reduce new launch sales by 19%

Revived Bill (2021)

- Manufacturers in control of launch prices
- "Negotiation" only affects older products…
- …but sets no minimum price for HHS "negotiation"
- 95% excise tax still applies
- "Negotiated" drugs started at 10; ramp to 20
- Savings: $250 billion (White House estimate)

What's Possible for Drug Pricing?

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- "Build Back Better" Act original price tag: $3.5 trillion (July 2021)
  - Climate change, education, childcare, housing and health care
  - Pay-fors: tax the wealthy and corporations, plus Rx drug savings
- Scaled-down $1.7 trillion budget reconciliation passes House on Nov. 17, 2021. Health provisions include:
  - ACA subsidies extended to 2025
  - Drug pricing provisions (revived HR 3)
  - OOP caps on prescription drugs (and insulin specifically)
  - Medicare Part D benefit redesign
  - Repeal of Trump rebate rule

Build Back…Never?

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What's Possible for Drug Pricing?

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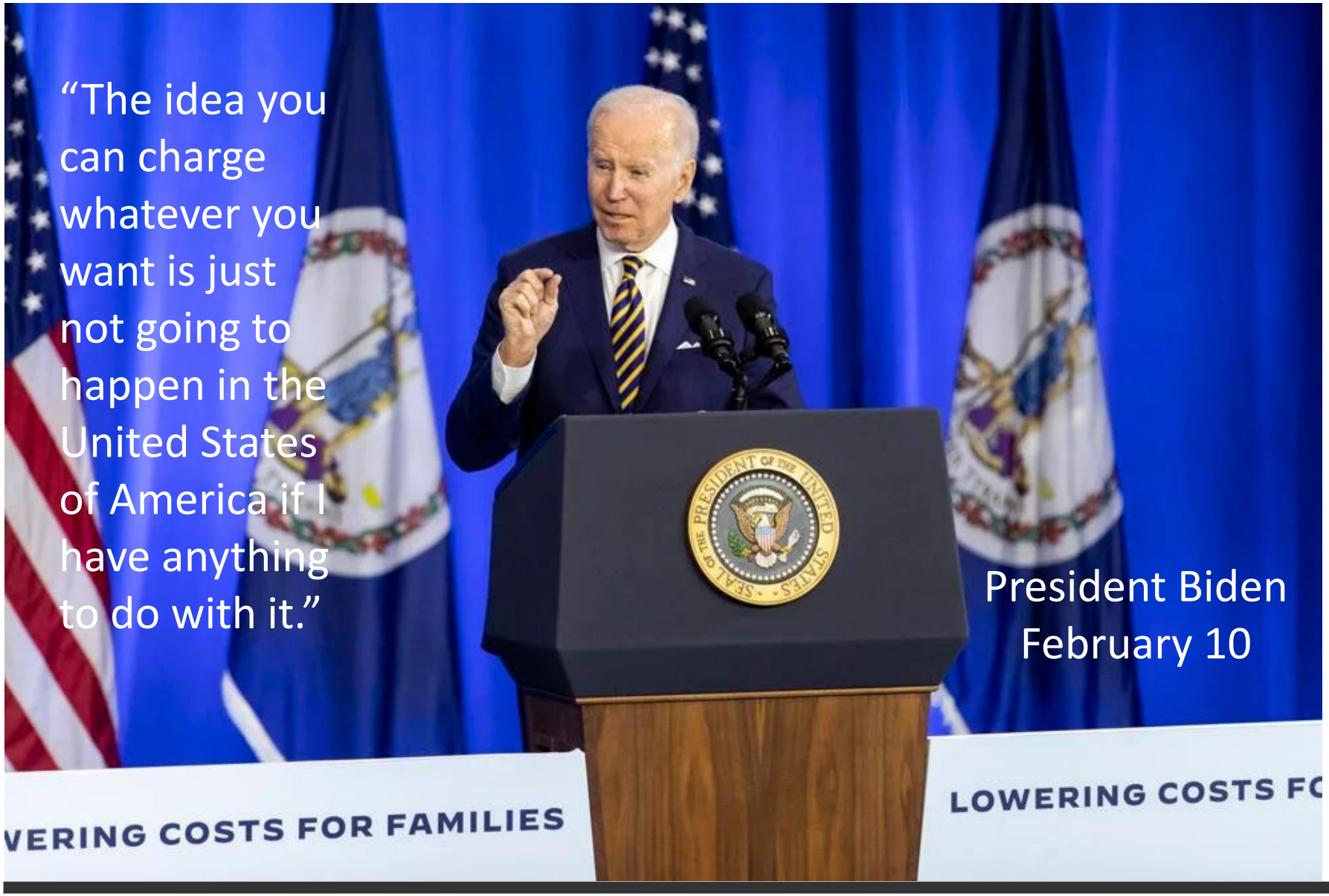

A “Better” BBB? What’s Possible?

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- The BBB passes after all, as is. (**Unlikely**)
- Democrats recraft BBB into a health care/drug pricing bill with a new name that drops price “negotiation” but focuses on things like Part D overhaul and insulin cap. (**More likely**)
- The push to pass BBB ends in failure; drug pricing is carried forward as a campaign issue. (**Most likely**)

Three Wins For The Affordable Care Act

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2010: Congress passes Affordable Care Act

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

2015: Upholds ACA a second time in *King v. Burwell* that tax credits can be extended to federal exchanges by 6-3 vote

2017: Congress eliminates the individual mandate

November 10, 2020: Oral arguments in *California v. Texas* over whether the ACA is unconstitutional without the individual mandate in place.

June 2021: 7-2 ruling to uphold ACA (again)

Looking Ahead: Health Priorities In 2022

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- COVID pandemic response with improved communication
- Pass some sort of health care/drug pricing reform legislation ahead of the mid-terms
  - Possible trimmed-down version with popular provisions that *could* yield bipartisan support (OOP insulin caps, Part D redesign)
- Continue to shore up the ACA (expanded subsidies)
- Ensure passage of PDUFA VII (and other user fee packages) and potentially ARPA-H/Cures 2.0
- Successfully confirm an FDA commissioner

Thank You!

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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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