Rob Califf, FDA, Confirmation Likely

Senate Committee Votes Jan 5

- **Rob Califf, MD should clear the necessary votes in Jan 5th Senate HELP (Chairwoman Murray, D-WA) full committee Executive Session (here).** Califf's confirmation will come after a nearly yearlong wait for a permanent FDA commissioner. Acting Commissioner Janet Woodcock's interim tenure ended on November 15 last year. Califf has gone on the record stating his support of government negotiation for lowering drug prices, accelerated approvals, and leveraging data to improve all verticals within the health care system.

- **FDA User Fee bills (UFAs) will be Califf's first job, and he will make his mark.** Califf must tackle reauthorization of the UFAs (2022 for FY23-27), where industry-impactful policies typically get tacked on. It's no secret that FDA receives industry fees to approve (or not approve) applications for new drugs, biologics, biosimilars, medical devices & diagnostics. Sen Burr (NC) noted that the fees have become exorbitant, which may weaken FDA's accountability to Congress.

- **Califf's immediate priorities include NEW Centers of Excellence, Supply Chain reforms, and improving the EUA process, given COVID lessons learned.**

    - **Dr. Califf may add a COE for Cardiovascular & Neurological Sciences.** He is a CV guy hence we could see the former, whole Alzheimer's and other potentially life-changing medicines are starting to flow through the agency The FDA currently has four Centers of Excellence in Regulatory Science and Innovation (CERSIs), along with others, for instance Centers of Excellence in Digital Health
    - **Califf has stated that the current supply chain is tenuous, and investment in advance manufacturing** is necessary to meet the urgent distribution needs precipitated by the pandemic.
    - **Reforming the emergency use authorization (EUA) process** to include inclusion of robust data that informs EUA designation. FDA was criticized for approving COVID therapies potentially too quickly but the agency knew it was in the middle of a PH crisis

- **Califf is a Big Data guy ..."In God we trust. All others must bring data."** Califf cites leveraging real world evidence (RWE) based on rigorous data analysis via digital health technology. Given Califf's experience in the healthcare and tech sectors; he could pave the way for an expedited review process for entities using innovative CT design, focused on diversity, and inclusion and outreach to marginalized populations. Notably, the FDA has faced significant criticism this year for some of its approvals that were predicated on homogenous clinical trials (Aduhelm-BIIB, Keytruda-MRK; Opdivo-BMY-see our prior analyses for more details).

- **Califf is a "fan" of the Accelerated Approval pathway, particularly for COVID-19 products and therapies.** Califf acknowledged the often scrutinized accelerated approval pathway has built in uncertainties, but is essential in meeting the urgent moment, especially for COVID-19 related products. He committed to streamlining the COVID test approval process if confirmed. He stated the FDA must invest in rigorous follow up once it grants accelerated approval and again cited technology as an essential tool in evaluating efficacy.

- **Califf supports lowering Drug Prices via Medicare negotiation and Patent Reform, but notes that is not FDA's purview**. Califf stated it's not FDA's role to weigh in on a drug's price but called out Medicare's ability to negotiate lower prices and eliminating legal tricks used by pharma co's that extend patents as policies he supports. If confirmed, he stated he would prioritize eliminating

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practices that block competition from generic and biosimilar entrants. Notably, Califf has received pushback on his potential conflicts of interest given his close industry ties (he's reportedly had consulting roles with MRK, JNJ, GSK, AZN, LLY, AMGN, ROG, Daiichi, SNY and BMY).

- **Califf says tech enabled CT diversity is critical to the integrity of FDA's process.** Califf acknowledged the challenges in including marginalized populations including rural communities, pregnant women, and children in clinical trials. He cited digital health platforms as promising for testing drugs that address mental health issues in hard to reach populations. Califf expressed his hopes the government will continue to fund CTs and allocate resources to scale innovative technology. He specifically lauded the inclusion of funding broadband access in rural communities in *Build Back Better Act (BBBA).*

- **UP NEXT/OUR TAKE**: The Senate committee (Chair Murray, D-WA) votes Jan 5 at 10 am ET in an Executive Session. The full Senate cotes thereafter. We think Califf will be confirmed, potentially by the end of the month, as 51 votes is a low bar. Some other thoughts at the moment:
  - **Califf inherits a COVID testing crisis.** His commitment to streamlining the COVID test approval process upon confirmation may come into play sooner than he anti. Americans are clamoring for COVID tests as Omicron rages. We could see his EUA reforms have an immediate, favorable impact on COVID testing manufacturers. (Abbott, Intrivo, OraSure, and Quidel and others).
  - **Opioids will undergo significant review under Califf's watch**. Califf spoke to the enduring tragedy of opioid addiction and laid out his plans for combatting the crisis. He said he would invest in prescriber education programs and a re-evaluation of current labels on opioid products and affirmed his commitment to address industry's role in promulgating the opioid crisis.
  - **Cross-agency -- FDA, CMS, NIH -- collaboration must be the new norm, but we will believe it when we see it, as other Commissioners have stated this.** Califf stated that alignment across federal agencies and with Congress, CMS and NIH in particular will be critical to FDA's success. He vowed to work across departments to ensure the FDA maintains its position as the "gold standard" in ensuring safety and efficacy.
  - **FDA Commissioner confirmation coincides with NIH Director Francis Collins' departure (December 2021)** Lawrence Tabak is named the acting director until an official replacement is named. Collins has openly opposed March-in rights and advocates for government investment in COVID-19 diagnostics. The new NIH Director and FDA Commissioner must co-navigate immediate polices that balance investments in innovation and equal, affordable access to essential therapies engagement and policy setting, particularly around IP.

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