Dr. Rob Califf Confirmed as FDA Commissioner

Priorities Going Forward

- **Robert Califf, MD, FDA Commissioner Nominee, was cleared by the Senate today.** He cleared cloture last night in the Senate with 49 votes (5 Republicans voted for Califf). Califf's confirmation comes after a 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.

- **NEW**; **Dr. Califf is a "fan" of the Accelerated Approval pathway, but calls for Reform.** He noted in an event with BIO President Michelle McMurray-Heath that clinical trial efficacy must be reaffirmed, with the creation of a centralized system to generate evidence. He has stated before the FDA must invest in rigorous follow-up once it grants accelerated approval and again cited technology as an essential tool in evaluating efficacy.

- **NEW: Dr. Califf's immediate priorities will likely 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 recognized Cardiovascular expert hence we could see the former COE, 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 knows 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 public health crisis

- **FDA User Fee bills (UFAs) will be Califf's first job in 2H 2022, and he will make his mark.** Califf must tackle reauthorization of the UFAs (Fall 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 calls himself a Big Data guy**. Califf cites leveraging real world evidence (RWE) based on data analysis via digital 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. 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). NOTE: see our prior analyses for more details here.

- **UP NEXT / OUR TAKE**: Concern over opioids and abortion politics may slow down the cadence of Califf's progress as FDA Commissioner. Califf will also be at the helm when the Aduhelm (FDA-Industry) investigation results are made public via OIG, per Janet Woodcock's request. Recently,

Contact Ipsita Smolinski - 202.250.3741 - Ipsita@capitol-street.com

Califf pledged not to work for industry 4 years post government service in order to obtain needed Senate votes, as members voiced concern about industry ties.

- **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.** Myriad past Commissioners have stated this sentiment. 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 confirmation coincides with NIH Director Francis Collins' departure (December 2021) an no nominee yet as well as OSTP leadership loss with Eric Lander's resignation.** 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.

- **Califf supports lowering Drug Prices via Medicare negotiation and Patent Reform, but notes that it 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 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 (Califf reportedly has had consulting roles with MRK, JNJ, GSK, AZN, LLY, AMGN, ROG, Daiichi, SNY and BMY).

Contact Ipsita Smolinski - 202.250.3741 - Ipsita@capitol-street.com