

BIO Vaccine Policy Steering Committee (VPSC) Meeting

April 3, 2025

Executive Summary – Key Highlights

- **Political Landscape**
 - Widespread concern over RFK Jr.'s anti-vaccine stance; members view him as a direct threat to public health.
 - FDA's April 2 RIF (reduction in force) marked a critical turning point, raising concerns about institutional stability.
 - Speculation about the Trump-RFK Jr. alliance, with potential for breakdown over conflicting interests.
- **Strategic Voices and Allies**
 - Dr. Oz seen as a potential "voice of reason" on public health within the current administration.
 - Senator Cassidy emerging as an influential advocate for CDC and public health engagement.
 - AEI and former Senator Richard Burr seen as important conservative allies in vaccine advocacy.
- **VPSC Leadership and Goals**
 - New co-chairs: Silvia Taylor (Novavax) and Art Hirt (Merck).
 - Emphasis on governance restructure, AEI relationship-building, and defining 2025 vaccine strategy.
 - Strategy centered on continuity, innovation access, and restoring public trust.
- **Investor and Market Challenges**
 - Vaccine development viewed as unpredictable and politicized; goalposts are constantly shifting.
 - Investor confidence shaken; limited capital access for the next 6–9 months.
 - Jim Wassil (Vaxcyte): no viable capital-raising opportunities in current climate.
- **Communications and Messaging Strategy**
 - Need to frame vaccine narrative around "efficiency," "transparency," and "national security."
 - Shift BIO's messaging regarding ACIP/FDA from defensive to proactive: from "protect" and "defend" to "optimize" and "enhance."
 - Launch of the pro-vaccine campaign "Why We Vaccinate" to be tested in the Washington, D.C. area.
- **Opportunities and Threats**
 - Threats: Anti-vaccine rhetoric, tariffs, index pricing, weakened FDA capacity.
 - Opportunities: Leverage National Security Commission report, onshore supply chains, reposition vaccines as national security assets.
- **Tactical Recommendations**
 - Engage conservative voices and grassroots/state-level influencers rather than federal figures like RFK Jr.
 - Convene a Senate Public Health Caucus.
 - Rebuild FDA capacity with Commissioner Makary; modernize review pathways while protecting mission integrity.
 - Focus public messaging on science and economic benefits—healthy workforce, national resilience.

Meeting Details

1. Meeting Goals
 - a. New governance structure of VPSC
 - b. Key areas for BIO engagement
 - c. VPSC goals/priorities
 - d. Build a relationship with AEI
2. Introduction of New Co-Chairs
 - a. Silvia Taylor – Corporate Affairs, Novavax
 - b. Art Hirt – SVP Vaccines, Merck
3. BIO is diversifying input to include Conservative voices.
 - a. American Enterprise Institute (AEI)
 - b. Richard Burr – former Senator NC; Advisor DLA Piper Health Policy Steering Committee
4. 2025 Vaccine Strategy
 - a. Goal: protecting continuity and viability of vaccine business
 - b. Core Principles: promoting access innovation and trust
 - c. Objective: maintain and strengthen environment for vaccine access and innovation
 - d. Objective: help build trust in vaccines
5. Impact of New HHS Administration
 - a. “it is time to go to The Hill and lobby that it is time for RFK Jr to go...communicate what’s going on in business”
 - b. Trump owed RFK Jr (for his support) but that loyalty may/may not last
 - c. There are now definitive examples of RFK Jr’s threat to vaccines and public health
 - d. If vaccine companies lose the confidence of investors – everyone loses
 - e. Jim Wassil, EVP & COO Vaxcyte
 - i. Investors have stated they are leaving until the next data read out.
 - ii. No opportunity to raise capital in the current environment
 - iii. Investors are sitting on the sidelines for next 6-9 months
 - iv. Vaccine pathway to approval is unpredictable and politicized
 - f. They (RFK Jr Administration) keep moving the goal posts on vaccines
 - g. BIO supports change, as long as the core mission of institutions are protected and there is business continuity
 - h. Need to communicate with the new Administration using their words – safety, efficiency, health resilience, transparency
6. John Crowley – BIO President & CEO
 - a. Vaccines are the #1 priority at BIO
 - b. Vaccines are “canary in the coal mine” with respect to gauging HHS anticipated actions
 - c. BIO created vaccine task force (1st BIO task force)
 - d. There are both threats and opportunities working with the new Administration
 - i. Threats
 1. Tariffs
 2. Index pricing
 3. Vaccine lack of trust
 - ii. Opportunities
 1. National Security Commission Report – Biotech Threats (<https://www.biotech.senate.gov/final-report/chapters/>)
 - a. Need for accelerated research and approval timelines
 - b. Need for on-shoring supply lines

- e. FDA needs to stay strong. Bio priority to work with Commissioner Makary to replace lost talent; modernize FDA; communicate big picture implications regarding vaccine access
 - f. Need a creative communication campaign targeting:
 - i. Legislators and influencers (as opposed to directly with RFK Jr)
 - ii. Conservative constituents such as AEI
 - iii. Unions (concern regarding Member health)
 - iv. Campaign needs to both inspire and frighten (potential outcomes)
 - v. \$2M of BIOs \$4M cash reserve will be spent on vaccine programs
 - g. Need to identify common ground areas
 - i. Domestic manufacturing
 - ii. Strategic importance to U.S.
 - 1. Need for a healthy population
 - 2. Protection from pandemic/bio attacks
7. Scott Gottlieb – Resident Fellow, AEI
- a. “MAHA movement is a cover for an anti-vaccine campaign”
 - b. Focus attention and dialog on grassroots/state/local level (vs Federal)
 - c. Very few people in the WH with public health backgrounds
 - d. Q: will the Trump-RFK Jr relationship break?
 - i. Not convinced it will break as there are non-vaccine issues, such as food safety, within MAHA
 - e. Q: how does one reach out and get support when no one is willing to stick their neck out?
 - i. Focus on the national security benefit – need for domestic manufacturing
 - f. Concern that companies are exiting smaller vaccine markets
 - g. Need to differentiate between anti-vaccine /vaccine hesitancy (“movable middle”) vs anti-vaccine mandate groups
 - h. Need to differentiate between science argument vs economic argument (healthy workforce)
 - i. Dr Oz can be public health voice of reason within WH
 - i. Has strong healthcare team
 - ii. Deeply scientific and public health minded
 - iii. Potential role educating the public
 - j. Senator Cassidy is getting more involved regarding CDC, etc
 - k. Recommend convening a Senate Public Health Caucus
 - l. Q: How work with AEI to target messages?
 - i. AEI is pro-vaccine
 - ii. Use as a data-leading voice to leverage the discussion
8. VPSC Strategy Discussion – ACIP and FDA
- a. BIO needs to change the messaging narrative from “protect”, “defend”, “maintain” to “support”, “shape”, “optimize”, “enhancing”, “streamline”, “efficiency”, “transparency”
 - b. Focus on positive change; no place for politics; areas of commonality
 - c. Move narrative to the middle
 - d. BIO Communications Strategy
 - i. Have built out a pro-vaccine campaign (whywewaccinate.org) based on qualitative and quantitative research
 - ii. Plan to market test in WDC market (April/May)
 - e. Re-imagining the FDA
 - i. Key messages working with FDA are “efficiency” and “speed”
 - ii. How does one approach the FDA given the brain-drain?
 - iii. Q: is Novavax (data requirements) the new review standard?
 - iv. Conflicting FDA objectives
 - 1. Drive to modernize

- 2. Slowing down vaccine development – eg, Novavax approval;
slow-walking ACIP
- f. More productive to target Makary and Trump Insiders vs RFK Jr
- g. Risk of U.S. losing its worldwide advantage in biotech by dramatically changing the FDA