# BIO Vaccine Policy Steering Committee (VPSC) Meeting April 3, 2025

## **Executive Summary – Key Highlights**

## • Political Landscape

- o Widespread concern over RFK Jr.'s anti-vaccine stance; members view him as a direct threat to public health.
- o FDA's April 2 RIF (reduction in force) marked a critical turning point, raising concerns about institutional stability.
- o Speculation about the Trump-RFK Jr. alliance, with potential for breakdown over conflicting interests.

#### • Strategic Voices and Allies

- o Dr. Oz seen as a potential "voice of reason" on public health within the current administration.
- o Senator Cassidy emerging as an influential advocate for CDC and public health engagement.
- o AEI and former Senator Richard Burr seen as important conservative allies in vaccine advocacy.

## • VPSC Leadership and Goals

- o New co-chairs: Silvia Taylor (Novavax) and Art Hirt (Merck).
- o Emphasis on governance restructure, AEI relationship-building, and defining 2025 vaccine strategy.
- o Strategy centered on continuity, innovation access, and restoring public trust.

#### • Investor and Market Challenges

- o Vaccine development viewed as unpredictable and politicized; goalposts are constantly shifting.
- o Investor confidence shaken; limited capital access for the next 6–9 months.
- o Jim Wassil (Vaxcyte): no viable capital-raising opportunities in current climate.

# • Communications and Messaging Strategy

- o Need to frame vaccine narrative around "efficiency," "transparency," and "national security."
- o Shift BIO's messaging regarding ACIP/FDA from defensive to proactive: from "protect" and "defend" to "optimize" and "enhance."
- o Launch of the pro-vaccine campaign "Why We Vaccinate" to be tested in the Washington, D.C. area.

## • **Opportunities and Threats**

- o Threats: Anti-vaccine rhetoric, tariffs, index pricing, weakened FDA capacity.
- o Opportunities: Leverage National Security Commission report, onshore supply chains, reposition vaccines as national security assets.

#### • Tactical Recommendations

- o Engage conservative voices and grassroots/state-level influencers rather than federal figures like RFK Jr.
- o Convene a Senate Public Health Caucus.
- o Rebuild FDA capacity with Commissioner Makary; modernize review pathways while protecting mission integrity.
- o 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 (1<sup>st</sup> 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
  - 1. 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 (whywevaccinate.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

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