

## **NVAC Innovation in Immunization Subcommittee Charge**

### **Background:**

Vaccines are one of the most important public health advances of our time. They have saved millions of lives by protecting individuals and communities against an array of diseases and dramatically reduce hospitalizations, deaths, and health care costs attributed to infectious diseases in the United States and globally. With further innovation and continued development, new and improved vaccines and delivery mechanisms may have an even greater impact on our society and will be critical to improving the public's health.

Historically, the public health need to prioritize vaccines such as COVID-19, measles, and polio vaccines has been clear given the burden of these diseases. This is also true for vaccines in the pipeline including universal influenza vaccines and respiratory syncytial virus vaccines. However, as vaccine developers target vaccines that will be recommended for smaller subsets of the populations, such as for *Clostridioides difficile* or vaccines made specifically for pregnant people, there will be different utilization models for these products than for universally recommended vaccines. These models will present challenges for vaccine developers so providing them with increased clarity of public health priorities and market demand for these targets could help these companies understand their investment risk for vaccine development.

More than ever, innovations in vaccine development, vaccination technologies, and programmatic changes (e.g., new vaccine platforms and antigens, microneedle patches, vaccination schedules, enhanced post-market vaccine safety monitoring systems) should align with public health priorities and practices in the United States and globally. The vaccine industry must make substantial investments to develop safe and effective vaccines and increased clarity of public health priorities and market demand can help the system overall.

### **Charge:**

The Assistant Secretary for Health charges the National Vaccine Advisory Committee (NVAC) with developing a report with recommendations outlining a vaccine innovation agenda that describes vaccine innovation priorities and actions for advancing the development of new and existing vaccines that will optimize public health and reduce disease burden in the United States.

To complete this assignment, NVAC should create a working group consisting of select NVAC members, federal and non-federal stakeholders comprised of ex-officio and liaison members of the committee, as well as experts not on the committee.

To complete the charge, NVAC should write a report that includes:

- A review of both conventional and promising novel approaches for vaccine discovery and development as well as recommendations for actionable, high-impact activities that HHS and federal partners can take to advance clinical trial design, regulatory requirements,

manufacturing processes, funding mechanisms, and business models; including ways we can leverage emerging technologies, processes, and workflows and suggestions for innovative collaborations.

- An evidence-based approach for identifying and prioritizing vaccine candidates and immunization technologies, including their criteria for prioritization. NVAC should take the potential impact on disease burden, population health outcomes, health equity, economic impact, national health priorities, and scientific feasibility into account in the development of the approach.
- A list of vaccination innovation priorities, including target antigens, molecular platforms, and immunization delivery technologies.
- A forward-looking approach to introduce vaccines for special patient populations and neglected diseases to portray their value and importance.
- A scientific agenda outlining a framework of research direction and identifies scientific needs and gaps that should be addressed by the end of 2028.

The final report from the NVAC should provide a concise summary of findings and be ready for vote by the February 2024 NVAC meeting. The report will also provide myself, and our partners, with important recommendations to spur innovation now and into the future. After NVAC approves this report, I charge NVAC with publishing an updated list of Vaccination Innovation Priorities every two years to adjust for changes in the immunization research and the development landscape. This new list will provide industry with clear guidance to support continued innovation.