

## NVAC Vaccine Safety Subcommittee Charge

### BACKGROUND

The United States has an extensive, long-standing, and multifaceted safety monitoring system designed to rapidly identify vaccine safety signals, minimize adverse events from vaccination, and ensure the public's confidence in vaccination. Consistently evaluating and optimizing the vaccine safety system is critical in maintaining a strong immunization system.

There have been several previous federal and non-federal efforts to enhance this system, such as the HHS Vaccine Safety Action Plan, which was endorsed by the National Vaccine Advisory Committee (NVAC) in January 1999. Additionally, to highlight the importance of vaccine safety, the [Vaccines National Strategic Plan 2021–2025](#), provides guidance in Goal 2, to maintain the highest levels of vaccine safety and effectively communicate the strengths of the U.S. vaccine safety system to providers, policymakers, and the public.

NVAC advises the Assistant Secretary for Health on ways to achieve optimal prevention of human infectious diseases through vaccination, provide direction to prevent adverse reactions to vaccines, and recommend research priorities and other measures to enhance the safety and efficacy of vaccines. NVAC previously evaluated and made recommendations on the state of the U.S. Vaccine Safety System (NVAC, 2011) as well as way to improve vaccine confidence (NVAC, 2015).

### CHARGE

To build on the last NVAC report on the vaccine safety system, I ask NVAC to review previous vaccine safety efforts and provide recommendations on which strategies should be maintained for continuous improvement of the vaccine safety system, as well as provide recommendations to build on new science, advancements in technology, and shifting public and partner expectations. While the committee has flexibility to address a variety of components of an effective system, I anticipate NVAC providing guidance on some of the following:

- Innovations to detect or investigate adverse events more quickly,
- Ways to provide better data about the underlying mechanisms of vaccine safety signals,
- New methods to prevent or capture administration errors,
- Guidance on improving transparency, communication, and knowledge of the process of weighing risks and benefits for vaccination,
- Approaches for improving timely access to vaccine safety data for researchers and analysts,
- Messaging strategies to support a more effective dialogue with health care professionals and patients,
- Evidence-based practices that encourage reporting of suspected adverse reactions, including recommendations to reduce the vaccine safety burden on health care providers,

- Methods to facilitate the timely exchange of vaccine safety information between federal, state, local, territorial, tribal authorities, and vaccine stakeholders,
- Pathways for the development of data sources to improve analytical abilities, such as provide racial and ethnic breakdowns, or increase our collective ability to detect safety signals, and
- Investments in additional education and training for health care providers on the prevention and treatment of vaccine-related adverse events.

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

The NVAC working group should:

- Review the last [NVAC report on vaccine safety](#), as well as a previous [vaccine safety scientific agenda](#) and the [vaccine safety goal](#) in the *Vaccines National Strategic Plan 2021–2025*, and outline opportunities for continual improvement of vaccine safety activities during vaccine development, licensure, and post-market use,
- Make recommendations to address current and emerging vaccine safety challenges, minimize preventable vaccine-related adverse events, and improve all the individual components needed for a strong safety system,
- Provide direction to improve coordination and stakeholder input into the timely detection and assessment of vaccine safety signals to better inform clinical decision making and public health policies,
- Describe science-based activities that HHS and federal partners can take to increase knowledge and use of the vaccine safety system, and
- Write a succinct report summarizing your findings.

NVAC should complete this charge so the report and associated assignments can be voted on before or during the June 2023 NVAC meeting.