



September 23, 2020

Admiral Brett P. Giroir, MD  
Assistant Secretary for Health  
Department of Health and Human Services  
200 Independence Avenue SW, Rm 701-H  
Washington, DC 20201

Dear ADM Giroir:

As the nation faces the most serious pandemic in a century, high confidence in COVID-19 vaccines will be critical to achieving high uptake of these vaccines. The National Vaccine Advisory Committee (NVAC) writes to urge immediate action to take proactive steps to build public confidence in COVID-19 vaccine development, safety processes, approval, and recommendation criteria. Accelerating the development, manufacturing, and distribution of candidate vaccines is a key component of the U.S. Department of Health and Human Services' (HHS) strategy to control the SARS-CoV-2 pandemic. To ensure acceptance and uptake of the vaccine, gaining the trust and confidence of the American people in the processes and systems that lead to the approval of safe and effective COVID-19 vaccines is critical.

Therefore, NVAC offers five recommendations to ensure high public confidence in key processes leading to very safe and effective future COVID-19 vaccines to achieve optimal uptake:

**Recommendation 1. Make safe and effective COVID-19 vaccines available to the public through the Food and Drug Administration's (FDA) Biologics License Application (BLA) process and use caution if using expedited processes.** The BLA process is the world's gold standard path to vaccine licensing. Its rigor and requirement for comprehensive data on vaccine safety, efficacy and manufacturing promotes clinician and public trust and fosters confidence in vaccine recommendations. The BLA process has an extraordinary record of accomplishment for releasing very safe and effective vaccines to the public.

If the U.S. uses an expedited process to speed access to COVID-19 vaccines, such as an Emergency Use Authorization (EUA) or an Expanded Access Program (EAP), great caution should be exercised. Prior to vaccine availability, input from relevant federal advisory committees is recommended and included recommendations for the most appropriate use of an emergency authorized vaccine for both prioritized, high-risk populations as well as the public. All safety and efficacy decisions, and the processes for making these decisions, should be fully transparent and communicated in a clear manner to the public to strengthen

confidence in such expedited approaches. Any expedited mechanisms should also detail their impact on concurrent and future Operation Warp Speed clinical trials so that novel vaccines will continue to be developed.

**Recommendation 2. Rapidly deploy and coordinate assets in vaccine safety monitoring through a federal immunization safety task force.** The 2009-10 H1N1 monovalent influenza vaccine safety efforts provide a model for the expansion of routine safety monitoring for a pandemic vaccine and coordination of federal assets in vaccine safety monitoring (e.g., the Vaccine Adverse Event Reporting System and administrative databases such as the Vaccine Safety Datalink, Sentinel Post-Licensure Rapid Immunization Safety Monitoring Program, Centers for Medicare and Medicaid Services, Department of Defense and Veterans Administration, and individual case review through the Clinical Immunization Safety Assessment network). It will be critical to ensure that post-approval safety surveillance is capable of rapidly and credibly defining the safety profile of COVID-19 vaccines using every system available to the U.S. government and globally, in a coordinated manner.

**Recommendation 3. Promptly create a unified, proactive, highly visible communication structure to regularly inform the American public about COVID-19 vaccine development, safety processes, approval, and recommendation criteria.** To build the public's confidence in COVID-19 vaccine development, licensing and recommendations, it is critical to ensure a broad understanding of these processes through frequent, consistent, and visible communication, including forums where the public can ask questions about the process. Therefore, NVAC recommends charging a group of HHS experts, such as leaders of Operation Warp Speed, the FDA, National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), to provide weekly updates to the media and the public on the status, timeline, and emerging information related to COVID-19 vaccine development, safety processes, approval, and recommendation criteria. All HHS COVID-19 vaccine communication efforts should adhere to the HHS National Vaccine Plan communication processes and principles.

**Recommendation 4. Establish an independent group of vaccine and public health experts (e.g., the National Academies of Science, Engineering, and Medicine) to conduct ongoing, rapid reviews of available data from the federal safety monitoring systems.** Make the findings and reviews available in real time to HHS leadership, relevant federal advisory committees, and the public. NVAC recommends this independent group of outside experts advise the Assistant Secretary for Health and the Assistant Secretary for Preparedness and Response on the presence, investigation, interpretation, and implications of possible side effects of COVID-19 vaccines. As an advisory group, the committee would assess risks, and could recommend ways to distinguish unrelated occurrences from true vaccine reactions, anticipate and respond to coincident events, evaluate side effects

associated with a vaccine, and recommend ways to publicize the Countermeasures Injury Compensation Program.

**Recommendation 5. Conduct community and stakeholder engagement to inform COVID-19 vaccine-related policies and to increase the likelihood that these policies will be supported by communities and groups disproportionately affected by COVID-19.** As the SARS-CoV-2 pandemic has amplified already existing health disparities, COVID-19 vaccine policies must address the needs of populations who are disproportionately affected by the pandemic. NVAC recommends engaging with representatives from communities and populations of interest to leverage the knowledge, skills, trust within the communities, and expertise to listen to their concerns; share resources; and ascertain their values, priorities, and beliefs related to COVID-19 vaccine development, licensing, acceptance and widespread uptake in order to inform policy and practice decisions. Vital information received during community and stakeholder engagement can be used to provide the necessary technical assistance and support to community representatives in their direct service efforts to build public confidence in the COVID-19 vaccines.

Gaining the confidence of American people in the multifaceted and complex processes that lead to the approval of safe and effective COVID-19 vaccines is critical to the acceptance of COVID-19 vaccines. Today, NVAC reviewed, discussed, and approved this letter and the five recommendations outlined in it, all of which need appropriate resources, including budget and staff. We believe these recommendations will help to ensure the nation is strategically positioned during this unprecedented time, to meet the urgent need for ensuring high confidence in COVID-19 vaccines.

Sincerely,

Robert H. Hopkins Jr., MD, MACP, FAAP  
NVAC Chair

John Dunn, MD, MPH  
NVAC Vaccine Confidence Subcommittee  
Co-Chair

H. Cody Meissner, MD  
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