

November 17, 2020

Alex Azar, JD
Secretary
U.S. Department of Health and Human Services

Chris Miller
Acting Secretary
U.S. Department of Defense

Moncef Slaoui, MD
Chief Advisor
Operation Warp Speed

General Gustave F. Perna
Chief Operating Officer
Operation Warp Speed

Dear Secretary Azar, Acting Secretary Miller, Dr. Slaoui and General Perna:

On behalf of the undersigned organizations, we write to commend the significant efforts that you and the other members of Operation Warp Speed (OWS) are making to prepare for deployment of one or more safe and effective vaccines for the SARS-CoV-2 virus and to offer recommendations for maximum vaccine uptake.

Food and Drug Administration (FDA) licensure or authorization of a SARS-CoV-2 vaccine is only the first step in ensuring that a safe and effective vaccine will be deployed. Our organizations have years of expertise in developing science-based recommendations and policies for the use of safe and effective vaccines for use in the United States including evaluating the benefits and harms of a vaccine, and values and preferences of the people affected. This expertise includes partnering closely with federal agencies, such as the FDA, National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), whose responsibilities lie in creating the parameters by which any vaccine is studied, evaluated for safety and efficacy, and administered to the people of the United States. For example, the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA) and the American College of Physicians (ACP) work with the Advisory Committee on Immunization Practices (ACIP) at the CDC to develop the annual childhood and adult immunization schedules. Those decades of first-hand experience have shown us that simply developing a vaccine demonstrated to be effective in highly controlled clinical trials is only the beginning of the deployment process.

For a vaccine to be most effective at the individual and population levels, the FDA must adhere to its longstanding, transparent requirements for evaluating risks and benefits in all sub-groups of the population for whom the vaccine may be beneficial. Ensuring the availability of adequate data for this purpose and transparency has been central to building public confidence in vaccine safety and efficacy that are critical to successful vaccine delivery. Further, partnership with and investment in our public health infrastructure and vaccine providers will also be essential. There is also a need to examine and develop new methods of public engagement for different populations in order to increase public confidence and uptake of an eventual vaccine.

In the October 2020 FDA Guidance for Industry on Emergency Use Authorization (EUA) for Vaccines to Prevent COVID-19, the FDA issued standards it expects COVID-19 vaccine

candidates to meet. In addition, the FDA has made clear that a positive recommendation from the FDA Vaccines and Related Biological Products Advisory Committee would be a necessary prerequisite to granting an EUA. These steps are important because authorizing a vaccine that has not been thoroughly vetted in a transparent fashion and demonstrated to be safe and effective would result in a significant lack of confidence among the scientific and medical community and the American public, seriously damaging vaccine delivery efforts.

After FDA approval, the ACIP has an essential role developing evidence-based recommendations for clinicians on vaccine use. ACIP is comprised of independent scientists, physicians, and lay people who advise the CDC regarding the specific populations who should receive a given vaccine, dosage and dosing intervals, and safety considerations such as contraindications during vaccine administration. ACIP members and liaisons undertake a deliberative assessment of benefits, safety and efficacy, harms, values, and preferences, based upon data from clinical trials, especially those used to obtain FDA approval. This evaluative process leads to assurances for the American scientific and medical communities, as well as the public, that the recommendations are based upon sound science.

To further build public confidence, we must undertake significant efforts to educate physicians and other vaccine providers about the data supporting a vaccine's approval. These frontline experts will be among our most important messengers to instill confidence among the general public. Clinicians have to be confident in the data they are presented in order to recommend their patients take the vaccine and to be able to answer questions their patients may have about the vaccine and the development process. Without a high percentage of Americans being willing to get a SARS-CoV-2 vaccine, the best vaccine delivery system in the world will not achieve the results we need.

The acceptance of a SARS-CoV-2 vaccine by the American public will have profound impacts on the ability of pediatricians, family physicians, internists, obstetricians, nurses, and other clinicians to successfully administer other routine childhood and adult vaccinations. Unfortunately, fear and mistrust of routine immunizations has been on the rise in this nation largely due to a vocal, well-established, and growing anti-vaccination movement that spreads misinformation about vaccines on social media platforms and through nation-wide speaking tours. This movement has already targeted a possible SARS-CoV-2 vaccine and is actively promoting disinformation about a potential vaccine and contributing to the large numbers of Americans who say they are hesitant to receive a vaccine once one is available. Distributing a SARS-CoV-2 vaccine before there are sufficient data available through safety and efficacy studies of optimal duration, and analyses have been conducted, will have long-lasting collateral damage to the percentage of Americans who will be willing to allow their children to be vaccinated under the recommended immunization schedule established by ACIP and approved by the AAP, AAFP, ACOG, and ACP. It could also decrease the number of adults and seniors who choose to get vaccinated, whose rates are already low. As such, it is imperative that the FDA, ACIP and CDC are allowed to fulfill their missions, guided by the established scientific protocols, and properly evaluate the safety and efficacy of all SARS-CoV-2 vaccines.

Our organizations stand ready to partner with OWS, the FDA and the CDC to ensure that an authorized or licensed SARS-CoV-2 vaccine is vetted and approved through the normal process

of ACIP deliberation so that your mission to eliminate SARS-CoV-2 infection in the United States, which in truth is all of our mission, will succeed.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American College of Obstetricians and Gynecologists
American College of Physicians
American Medical Association
Infectious Diseases Society of America
Pediatric Infectious Diseases Society