



October 30, 2020

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases
1600 Clifton Road NE
MS-H24-8
Atlanta, GA 30329

Re: October Meeting, Docket Number CDC-2020-0100

Dear Members of the Advisory Committee,

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 136,700 family physicians and medical students across the country, I appreciate the opportunity to provide comments to the Advisory Committee on Immunization Practices (ACIP). The AAFP strongly supports the work of the ACIP and have appreciated our long-standing relationship and collaboration. The work of ACIP is critical to the practice of family medicine and we are grateful for the Advisory Committee's ongoing efforts related to the development and eventual distribution of a COVID-19 vaccine.

Family physicians are serving on the frontlines of the COVID-19 pandemic and have seen firsthand the inequitable impact that COVID-19 has had on their patients and communities. Family physicians are also uniquely aware of the impact that vaccine hesitancy and public perception have on the effectiveness of immunizations. As such, the AAFP has set forth some basic guiding principles for COVID-19 vaccine development including:

- The vaccine development and approval process must be fully transparent and not circumvent regulatory standards.
- Any trials involving vaccine candidates must adhere to standards that ensure safety and effectiveness, and a successful vaccine candidate must demonstrate these before being authorized by the Food and Drug Administration (FDA) and recommended by the ACIP.
- All safety and efficacy data should be reviewed by both FDA and independent vaccine experts (like the ACIP), all of whom must support the authorization or licensure of a COVID-19 vaccine.
- COVID-19 vaccines should be studied in the populations for whom they are intended, including, but not limited to, Black, Indigenous, Hispanic, Latinx, Asian American, Native Hawaiian, Pacific Islanders, and other populations that face inequitable health outcomes and who have been disproportionately impacted by the pandemic such as:
 - Health care and other essential workers,
 - People with chronic conditions who are at greatest risk of serious illness and death due to COVID-19,

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- Children, pregnant women, and other populations in whom vaccines may perform differently, and
- Elderly individuals.
- Vaccines must be distributed in an equitable manner and prioritize individuals who are at a high risk of COVID-19 infection and severe COVID-19 disease, including the aforementioned populations.
- Vaccine distribution plans must include timely information and resources for family physicians and other primary care providers, who are essential in counseling patients about vaccines and combatting vaccine hesitancy.

The AAFP acknowledges the COVID-19 pandemic continues to be a public health crisis and the urgency with which it needs to be addressed. However, in order to ensure a vaccine is safe and effective, and is accepted by the public, vaccines must be developed in a transparent, rigorous process that is not politicized or rushed. We commend the ACIP for continuing to hold meetings that are open to the public to discuss these important issues. In addition to the basic principles described above, the AAFP would like to point out additional concerns regarding the vaccine development and distribution process for the Advisory Committee's consideration.

First, we are concerned with the relatively short two month follow up time period that is being used as a threshold for emergency use authorization (EUA). Although the AAFP recognizes that this time period was chosen because immunization reactions typically occur within the first six weeks after vaccination, we are concerned that the median of two months will not be sufficient to observe potential vaccine reactions across study participants. This is particularly important as to date many trials have not enrolled a representative number of individuals from groups that have been historically underrepresented in clinical trials. Given the inequitable impact of COVID-19 on Black, Indigenous, and Latinx people, a lack of representation and data on safety and efficacy in these groups may further erode the trust in the vaccine development process. By using a shorter endpoint, the trials may be unable to adequately observe safety and efficacy in these populations. There is an additional concern that provision of EUA prior to completion of the clinical trials will lead to huge numbers lost to follow up as participants in the placebo arm may opt to drop out of the trial to receive the vaccine. Together, these concerns may result in incomplete trial results, particularly for at-risk populations, and additional challenges to full licensure of a vaccine.

Additionally, the AAFP agrees with several concerns voiced at the recent FDA Vaccine and Related Biologics Advisory Committee (VRBAC) meeting related to the primary endpoint of mild COVID-19 disease not accurately reflecting efficacy of vaccine candidates on severe cases of COVID-19. If a vaccine is not as efficacious in preventing severe COVID-19 disease, it could exacerbate the inequitable impact that COVID-19 is currently having on Black, Latinx, Indigenous, and other at-risk populations. While mitigation strategies (handwashing, masks, social distancing) will continue to be recommended, the reality is that many people will not adhere to the strategies once vaccinated increasing the number of severe cases of COVID-19.

Given the vital role that family physicians will play in counseling patients on the safety and efficacy of a COVID-19 vaccine, the AAFP strongly recommends distribution plans consider the role of primary care physicians in education and counseling of patients in the first phases of vaccine distribution, even if they are not directly involved in administering the vaccine. Timely and consistent education and resources will be important to increase vaccine confidence among

physicians and their patients. Effective vaccine counseling will require that family medicine physicians are equipped with accurate data on vaccine safety and efficacy across populations, as well as other information that could aid in answering patients' questions. The FDA and CDC should implement a process for communicating the latest information with primary care physicians.

Thank you again for the opportunity to provide comments to the ACIP. The AAFP commends the CDC and ACIP for their ongoing efforts to ensure that our nation will benefit from a safe and effective COVID-19 vaccine. We stand ready to partner with you in ongoing and future efforts to ensure equitable access to a vaccine once it is available. Should you have any questions, please contact Dr. Melanie Bird, PhD, Clinical and Health Policy Manager at mbird@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "Gary A. LeRoy, MD, FAAFP". The signature is written in a cursive style with a large, stylized "G" and "L".

Gary LeRoy, MD, FAAFP
Board Chair