



August 26, 2020

Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter Marks, M.D, Ph.D.
Director
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn and Director Marks:

On behalf of the Infectious Diseases Society of America (IDS A) and HIV Medicine Association (HIVMA), we thank you for your leadership in our nation's response to COVID-19 and particularly in overseeing Operation Warp Speed. The independent decision-making power and scientific rigor for which the Food and Drug Administration (FDA) is well respected are of critical importance now, as scientists work tirelessly toward the development of safe and effective COVID-19 vaccines. We wholeheartedly agree with the commitments you set forth in your article, "[Unwavering Regulatory Safeguards for COVID-19 Vaccines](#)." We would be pleased to assist you with your efforts.

From our perspectives on the frontlines of this pandemic, caring for patients with severe illness due to COVID-19, we greatly appreciate the desire to make a vaccine available as quickly as possible. Many of our members are working on COVID-19 vaccine clinical trials, prioritization, and distribution plans, and IDS A is working to support these efforts as well. However, making a vaccine available before sufficient safety and efficacy data are available could significantly undermine COVID-19 vaccination efforts and seriously erode confidence in all vaccines in the current atmosphere of vaccine hesitancy and active efforts to undermine all vaccines, including any found safe and effective for COVID-19.

IDS A asserts that rapid full licensure of a COVID-19 vaccine is preferable to bringing a COVID-19 vaccine to market via an Emergency Use Authorization (EUA), particularly in light of public distrust of vaccines. At a minimum, a Phase 3 trial should be completed prior to widespread use. However, we recognize that FDA guidance on the development and licensure of vaccines to prevent COVID-19 could permit COVID-19 vaccines to come to market via EUA. We want to underscore that it is critical that FDA ensures sufficient safety and efficacy data are available and have been reviewed by internal as well as independent experts prior to granting an EUA. The very safeguards which your article emphasized are still crucial for the approval of an EUA. Specifically, it is critical that data to support any authorization or licensure—including an EUA—reflect the diverse U.S. population, including communities of color and older adults who have been hardest hit by this pandemic. Further, we agree that transparent discussion and thorough review and analysis of available data at FDA's Vaccines and Related Biological Products Advisory Committee is essential prior to vaccine authorization or licensure. We also agree that postmarket surveillance of COVID-19 vaccines will be very important.

Unfortunately, there remains significant work to be done to build public confidence in vaccines in general, and specifically in a COVID-19 vaccine. Recent polls have found that as few as 50% of Americans are committed to getting a COVID-19 vaccine, and some of the communities most heavily impacted by the pandemic may be particularly wary of a COVID-19 vaccine. IDSA is committed to working with our federal and non-government partners to boost vaccine confidence and uptake, and robust data supporting a vaccine's approval will be the critical foundation for this effort. While we believe that meeting the requirements for full approval is the surest route to maximum public trust and vaccine uptake, if a COVID-19 vaccine is made available via EUA, some specific actions may be necessary to shore up public confidence. Clear, consistent public messaging explaining the difference between an EUA and traditional approval will be important. Further, an informed consent process that explains why the vaccine is only available under an EUA will be critical.

Once again, we thank you for leadership and urge you to maintain FDA's independent decision-making and scientific rigor, which serve as the foundation for the American public's confidence in our medical products. Cutting corners with respect to the evaluation of safety and effectiveness must not be done. If we can do anything to assist you, please contact us through Amanda Jezek, IDSA's Senior Vice President, Public Policy & Government Relations at ajezek@idsociety.org or Andrea Weddle, HIVMA's Executive Director aweddle@hivma.org.

Sincerely,



Thomas M. File, Jr., MD, MSc, FIDSA
President, IDSA



Judith Feinberg, MD, FIDSA
Chair, HIVMA