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Vaccines and Related Biological Products Advisory Committee
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

October 15, 2020

Dear Committee Members,

On behalf of the Infectious Diseases Society of America, an organization representing over 12,000 infectious diseases physicians and other clinicians, scientists and public health experts, its HIV Medicine Association, and the Pediatric Infectious Diseases Society, we appreciate this opportunity to provide input to the Vaccines and Related Biological Products Advisory Committee. We urge the Committee to recommend the authorization or licensure of a COVID-19 vaccine only when it meets existing U.S. Food and Drug Administration (FDA) licensure standards or recommendations set forth in the October 2020 guidance for industry on Emergency Use Authorization (EUA) for vaccines to prevent COVID-19, and when independent experts concur that the standard has been met. We share FDA's goal of making available a safe and effective COVID-19 vaccine as a critical tool to help end this pandemic as soon as those standards are met. Moreover, for a vaccine to control the pandemic, there must be a strong confidence in the vaccine and the process by the public and the health care community.

While we are encouraged by the rapid development of COVID-19 vaccines, the review process must be fully transparent and not circumvent existing regulatory standards. While we maintain that traditional licensure would be the preferable path for a COVID-19 vaccine, as licensure requires more substantial data demonstrating safety and efficacy, we acknowledge that some of the requirements in a biologics license application are time consuming and not uniformly critical for safety and efficacy. We appreciate the criteria set forth in FDA's October 2020 guidance. It is critical that an EUA be considered only if the recommendations in that guidance are satisfied. The guidance includes strong recommendations for developers that:

- Data from Phase 3 studies should include a median follow-up duration of at least two months after the completion of a full vaccination regimen;
- Placebo-controlled trials are continued once an EUA is issued and developers will address how to obtain follow-up information for study participants who withdraw in order to receive the EUA-approved vaccine; and
- Information regarding supply chain, distributors and manufacturer surge capabilities is provided.

We are also pleased to see that, in order to be eligible to receive an EUA, a vaccine must be separately evaluated by VRBPAC. Further, we believe that an EUA should require a positive recommendation from VRBPAC.

While the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) would typically review vaccine data shortly after FDA approval, we recommend that FDA share all allowable and available data about a vaccine

candidate with ACIP *prior* to making any decision about an EUA or licensure. This allows additional independent vaccine experts to provide input and will speed the ability of ACIP to provide recommendations for use. An FDA decision that is consistent with the independent scientific experts who serve on the VRBPAC and ACIP could help boost confidence in the vaccines that are ultimately authorized or licensed.

The October 2020 guidance and repeated statements from FDA Commissioner Hahn and Center for Biologics Evaluation and Research Director Marks emphasizing that decisions regarding the authorization or licensure of COVID-19 vaccines will be based upon transparent reviews of data are encouraging; however, a number of concerns and important questions remain that we urge the VRBPAC to carefully consider.

While we agree that clinical trials should continue after an EUA in order to continue gathering critical data on the vaccine's performance, we are concerned about the feasibility and ethical questions of keeping study subjects on a placebo after a vaccine is made available via EUA. The VRBPAC should insist that sponsors present a compelling case regarding their ability to continue studies following an EUA before recommending that FDA grant an EUA. Since additional placebo-controlled data may not be available or unbiased, the standard of evidence for issuing an EUA must be high. The standard that requires only that a medical product "may be effective" is inadequate for a vaccine that will be given to hundreds of millions of healthy people. It is also critically important to follow study participants for the durability of neutralizing antibody response. We must know what to expect in terms of the duration of infection so that appropriate messaging and planning for revaccination are put into place.

We are concerned that VRBPAC will likely face differing analyses due to the variation in definitions of primary endpoints among vaccine candidates. The VRBPAC should be provided with pre-specified outcome analyses designed for each vaccine, such as severe disease 14 days or more after the last dose, symptomatic disease with harmonized definition 14 days or more after the last dose, and hospitalization 30 days or more after the last dose. These should include subgroup analyses by gender, sex at birth, age group, and racial and ethnic population.

We encourage the VRBPAC to request that FDA provide the rationale for its decision in the October 2020 guidance not to conduct inspections of vaccine manufacturing facilities specific to these vaccines. VRBPAC should strongly consider whether this decision is appropriate or poses undue risk to the public.

We continue to emphasize that COVID-19 vaccines should be adequately studied in populations that have been disproportionately impacted by the pandemic and who face disparities in care, including the elderly; individuals with chronic conditions; and Black/African American, Indigenous, Latinx, and other communities of color. Additionally, children, pregnant women and other populations in whom vaccines may perform differently should be a priority. We are concerned that some trials may lack sufficient data across ages and racial and ethnic groups not sufficiently represented in clinical trials.

Recent polls have found that less than 50% of Americans are committed to getting a COVID-19 vaccine, down from 72% in May; some of the communities hit hardest by the pandemic may be particularly wary of a vaccine. Thorough and transparent review by FDA, VRBPAC and ACIP of data supporting a vaccine's authorization or licensure is the essential foundation to strengthen public confidence in a COVID-19 vaccine. Authorizing a vaccine that has not been shown through randomized clinical trials to be convincingly safe and effective in preventing disease could cause more harm by undermining COVID-19 vaccination efforts and further eroding public confidence in all vaccines and public health authorities. Even after a COVID-19 vaccine is approved, other infection prevention measures (including masking, social distancing, and hand hygiene) will remain critical as we scale up vaccine manufacturing and distribution, boost vaccine uptake, and continue to learn about a vaccine's long-term protection.

We thank you for your consideration of our comments. If you have questions or if you would like additional information, please contact Amanda Jezek, IDSA's Senior Vice President of Public Policy and Government Relations, at ajezek@idsociety.org, Andrea Weddle, HIVMA's Executive Director, at aweddle@hivma.org, or Christy Phillips, PIDS' Executive Director, at cphillips@idsociety.org.

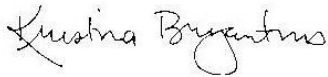
Sincerely,



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