September 28, 2020

Representative James E. Clyburn
U.S. House of Representatives
Select Subcommittee on the
Coronavirus Crisis
2157 Rayburn House Office Building
Washington, DC, 20515

Representative Steve Scalise
U.S. House of Representatives
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2157 Rayburn House Office Building
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Dear Chairman Clyburn and Ranking Member Scalise:

On behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA), we thank you for your leadership in our nation's response to COVID-19 and look forward to the Select Committee's October 2, 2020 hearing with Health and Human Services Secretary Azar to review national efforts to contain the coronavirus pandemic, which should be based on scientific evidence as provided by our nation's scientific and public health experts.

Evidence-based policies and decisions are essential for all aspects of the response, including the approval of COVID-19 vaccines. 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 set forth by FDA Commissioner Hahn and FDA Center for Biologics Evaluation and Research Director Marks in their article, "Unwavering Regulatory Safeguards for COVID-19 Vaccines."

From our perspective 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 IDSA and HIVMA are 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 vaccines, including any found safe and effective for COVID-19.

IDSA and HIVMA assert 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 widespread public distrust of vaccines. At a minimum, a Phase 3 trial should be completed prior to widespread use although we recognize that FDA guidance could permit COVID-19 vaccines to come to market via this mechanism. 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 emphasized in the article by Drs. Hahn and Marks 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 African American, Latinx, Native American, other 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, and that post-market 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. IDSA is committed to working with our federal and non-government partners to boost vaccine confidence and uptake, and robust data supporting approval will be critical for this effort. While we believe that meeting the requirements for full licensure 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 licensure 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 we hope you share our conviction 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
President, IDSA

Judith Feinberg, MD
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