July 29, 2020

General Gustave F. Perna
Chief Operating Officer
Operation Warp Speed
U.S. Department of Health and Human Services
Washington, DC

Moncef Slaoui, PhD
Chief Advisor
Operation Warp Speed
U.S. Department of Health and Human Services
Washington, DC

Francis S. Collins, M.D., PhD
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear General Perna, Dr. Slaoui and Dr. Collins:

We write on behalf of the Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA) to urge you to ensure that the sponsors of COVID-19 clinical trials for investigational vaccines or therapeutics do not exclude people living with HIV as candidates for study inclusion. We also urge you to ensure that there is a formal process in place to engage the communities who have been disproportionately impacted by the COVID-19 pandemic -- including African Americans, Latinx individuals, Native Americans and older adults -- in discussions of clinical trial design for vaccines and therapeutics, and to ensure that all trial participants represent the populations at highest risk. IDSA and HIVMA represent over 12,000 infectious diseases and HIV physicians, scientists, and other healthcare and public health professionals on the frontlines of the COVID-19 response.

Inclusion of People with HIV

We are very concerned that the exclusion criteria for the Moderna mRNA-1273 Phase 3 vaccine clinical trial specifically eliminates persons living with "human immunodeficiency virus (HIV) infection." There is no clinical justification for excluding people with treated, well-controlled HIV from COVID-19 vaccine trials. In fact, persons living with HIV have participated in a variety of vaccine trials including those involving "live" attenuated viral vaccines. With respect to COVID-19, studies have shown that persons with treated HIV do not have worse outcomes than persons who do not have HIV. If there are concerns that people living with HIV will have a unique immune response to the vaccine, this can be studied through a subset analysis of participants with HIV as should be done routinely for participants with other chronic conditions.

While the inclusion criteria state that adults with pre-existing medical conditions who are stable are eligible, the fact that persons with HIV are specifically excluded suggests that this does not apply to them even if their health status is excellent. This must be changed and clarified in all publicly available information for the Moderna trial including the clinicaltrials.gov website and with all participating sites. We are concerned that if the Moderna vaccine is approved by the U.S. Food and Drug Administration

(FDA) without safety or efficacy data in people living with HIV and that people with HIV will be not be included in the FDA-approved label and that insurers will refuse to pay for vaccination. We also are very concerned that other vaccine trial sponsors may follow Moderna's lead and exclude people with HIV. We strongly urge immediate action to ensure that well-controlled HIV is not listed as an exclusion criterion in this or any other COVID-19 vaccine or therapeutics trials.

Community Representation

We appreciate that NIH recognizes that enrollment in COVID-19 clinical trials for both vaccines and therapeutics must reflect the populations who have been disproportionately impacted by COVID-19. This is critical given that polling indicates that just 50% of Americans plan to get a COVID-19 vaccine when one becomes available, with just 25% of Black/African Americans and 37% of Latinx reporting that they plan to do so. To build trust among those highly impacted communities and avoid policies that can compromise the success of these trials, people with HIV or medically at-risk populations and community representatives must be involved from the start in the design of COVID-19 clinical trials and not just brought in at the end of study development to help recruit participants. All COVID-19 clinical trial sponsors must be held to this critical standard if they are to be successful in delivering data for effective therapeutics and vaccines to the FDA for approval for diverse range of U.S. subpopulations. As a recent example of the negative effects of inadequate community involvement in clinical trial design, in Oct. 2019, the FDA approved Descovy for HIV pre-exposure prophylaxis (PrEP) with no indication for cisgender women due to the absence of any clinical trial data for this key population.

While we understand that we are in the midst of a global health crisis like no other and appreciate the urgency in rapidly advancing COVID-19 clinical trials, the effectiveness of COVID-19 vaccines and therapeutics will be significantly diminished if they are not studied in diverse populations, and if they are not widely accepted by individuals in the U.S. and globally. With 39 million people living with HIV globally and approximately 25 million being on antiretroviral therapy, it is critical that they be included in trials and that we understand their response to COVID-19 vaccines and therapeutics.

We urge immediate action to ensure that COVID-19 vaccine trials do not exclude people with HIV, including the NIH and Moderna mRNA-1273 Phase 3 study that just began enrolling participants this week. In addition, we strongly urge that significant work be done to seek early and ongoing input on clinical trial design and recruitment strategies from the communities that have borne the brunt of the COVID-19 pandemic. When a vaccine becomes available, community input will be critical to informing distribution and supporting vaccine uptake.

We would appreciate the opportunity to discuss these issues with you as the important work of identifying effective vaccine and therapeutics proceeds at a record pace. We may be contacted through the IDSA Senior Vice President of Public Policy and Government Relations at ajezek@idsociety.org and the HIV Medicine Association Executive Director Andrea Weddle at aweddle@hivma.org.

Sincerely,

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