Public Comment from Mitchell Warren, Executive Director, AVAC
At the Vaccines and Related Biological Products Advisory Committee (VRBPAC)Meeting
October 22, 2020,

My name is Mitchell Warren, and I am the Executive Director of AVAC, a non-profit organization founded in 1995 to accelerate the ethical development and global delivery of HIV vaccines and other new prevention options. In March, we joined with several organizations to establish the COVID-19 Advocates Advisory Board, a global partnership to engage civil society to accelerate R&D and eventually delivery of COVID-19 vaccines. I have no conflicts to declare, and we accept no funding from pharmaceutical companies.

I want to acknowledge and appreciate the FDA guidance documents on Licensure and on Emergency Use Authorization in June and October. Both documents set important criteria that should be viewed as the absolute minimum requirements for FDA action – and that any action requires this Committee's positive recommendation.

While this committee and the FDA are focusing on the US by statute, what happens today in this virtual room has global importance. No pressure, but what happens in the coming days, weeks and months through this process will either enable or inhibit our collective ability to translate any clinical trial result into ultimate global public health impact and to instilling confidence in vaccines and regulatory processes generally.

As you deliberate this afternoon and in subsequent meetings, we urge you to consider the following issues:

1. ***The critical importance of distinguishing between an Emergency Use Authorization (EUA) and licensure under a Biologics License Application (BLA) – and ensuring any EUA places specific requirements for continued data collection and clearly articulated pathway and timeline for a full BLA.***

If an EUA is granted based on strong scientific evidence, the Committee and FDA must make clear that EUA is not in lieu of an approval; a signal that licensure is imminent or guaranteed; or promoted or described as a "pre-license". Further, the FDA should place strict requirements on the continued collection of data in the ongoing, blinded clinical trials that would be required for any possible future BLA, and the applicant should be required to present a timeline for the submission of such BLA.

2. ***The need for the inclusion of diverse populations in COVID-19 vaccine trials and the accrual of relevant safety and efficacy data in diverse populations, including especially those groups most impacted by COVID-19 already, and across the full age range of potential vaccine recipients.***

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If an EUA or BLA application does not provide adequate diversity across age and population, the Committee and the FDA should determine strict requirements to place on the applicant to provide these data as part of the application process. A partial authorization or approval for only some populations will further diminish trust and confidence in the research and regulatory enterprises.

3. The importance of broad community engagement in the development and implementation of vaccine trial protocols and in the review of applications for vaccine authorization and licensure.

Any COVID-19 vaccine that proves safe and effective will need to be introduced on a scale and with a speed never previously seen. It is essential, therefore, that communities both have confidence in the regulatory process, and that the vaccine meets the needs of the populations it will serve, in terms of safety and efficacy as well as in accessibility and ease of use. To achieve these goals requires robust and informed community engagement throughout all these processes, and there are strategic ways community and other advocates can be involved throughout the research process that will safeguard conduct of clinical trials, and importantly, prepare for rollout, access, and wide uptake – and we urge the FDA to support inclusion of civil society and community perspectives as part of the regulatory process and future Committee meetings.

4. Clarifying implications of initial authorization or licensure of one vaccine on the design and conduct of future COVID-19 vaccine trials.

As the Committee and the FDA prepare to review applications from the first COVID vaccines in development, it will be critical to consider the implications for ongoing and future efficacy trials if and when a vaccine meets or exceeds the 50% efficacy threshold as outlined in the Agency's guidance documents. Issues will arise regarding how to approach the control arms and overall trial designs, and we encourage the FDA to develop an additional FDA guidance document to help guide these discussions.

In conclusion, AVAC calls on the VRBPAC and the FDA to reaffirm its commitment towards transparency, independence, evidence-based scientific decision making and inclusion of affected populations as part of vaccine development for any candidate being submitted for either an EUA and a BLA.

Thank you again for the opportunity to present today and for your commitment to scientific and regulatory processes that move at the speed of trust.

Full comments submitted in writing and available here.