Public Comment from Mitchell Warren, Executive Director, AVAC
At the Vaccines and Related Biological Products Advisory Committee (VRBPAC)Meeting
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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 global COVID-19 Advocates Advisory Board. I have no conflicts to declare, and we accept no funding from pharmaceutical companies.

AVAC welcomes the safety and efficacy data of the Pfizer/BioNTech mRNA vaccine candidate. This is terrific news to be sure, and a triumph of science and partnership.

While the data – to us – do clearly warrant an EUA, they also require the maximization of additional data collection to address a number of remaining questions and issues that need to be addressed:

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

2. There continues enormous need for the inclusion of diverse populations in COVID-19 vaccine trials generally and the data under review today provide limited information about the safety and efficacy data in diverse populations, including people living with HIV; other immunocompromised people; and those who are pregnant or breastfeeding. It is essential that specific requirements and timelines be articulated so that these key populations are not left behind. And I want to underscore Lynda Dee's earlier comments on the equity, diversity and inclusion in research and review.

3. With only two months of follow-up data (as per the guidance for EUA), it is essential that a future BLA include at least six months of follow-up. Therefore, continued blinded follow-up of the trial is warranted, while recognizing that some trial participants will exercise their right to leave the trial and, if from the placebo group, seek vaccination. If an EUA is granted it will be urgent for the FDA and the companies to rapidly develop clear information, including an explicit re-consent process, to outline the benefits, risks and rights of maintaining the blind for both public health and personal benefits, and strongly encourage you to endorse the deferred, blinded-crossover design proposed by NIAID and presented earlier today.

   In addition to maintaining the blind of the current Pfizer/BioNTech trial, the Committee and FDA should clarify implications of an EUA on the design and conduct of ongoing and future COVID-19 vaccine trials. Issues will arise regarding how to approach the control

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arms and overall trial designs, and we encourage the FDA to develop an additional guidance document now to help guide these discussions.

4. Perhaps the biggest unknowns remain questions of the **durability of vaccine efficacy** and **whether this vaccine prevents asymptomatic disease and will limit transmission**. A clear plan to collect and communicate information to inform answers from within the ongoing efficacy trial as well in the design of additional trials is essential and should be clearly articulated when any EUA is announced – and should be strategically linked to other vaccine developers to jointly identify correlates, bridge data to other populations and platforms and track use.

   As we have seen repeatedly throughout this pandemic – and in 40 years of the HIV pandemic – clear, evidence-based, scientifically-accurate information must be the cornerstone of our collective response.

In conclusion, AVAC applauds this mRNA vaccine and both this VRBPAC and the FDA for its commitment towards transparency, independence, evidence-based scientific decision making. This process is not just about authorization or approval; it is a beacon of independent review and transparency that will help foster the trust necessary to re-build confidence in vaccines, in science and in our public institutions. 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 from October 22nd available here.
More information about COVID vaccines at https://www.avac.org/covid/.
More information about the COVID Advocates Advisory Board at https://covidadvocates.org.