FDA Advisory Committee, VRBPAC, Holds Public Covid-19 Vaccine Development Meeting

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On October 22, a Food and Drug Administration (FDA) advisory group, Vaccines and Related Biological Products Advisory Committee (VRBPAC), and Center for Biologics Evaluation and Research's (CBER) held a 9-hour meeting to discuss the authorization of a COVID-19 vaccine. This meeting highlighted what is known about COVID-19 and touched on major key points and challenges facing vaccine development and distribution: how trials will be conducted in terms of safety and efficacy in the event of an Emergency Use Authorization (EUA), instilling the public's trust in the vaccine, and the inclusion of underserved minority groups and high risk populations.

The safety and efficacy of a COVID-19 vaccine raised concerns and was discussed among the committee in yesterday's meeting. Dr. Doran Fink, Deputy Director in the Division of Vaccines and Related Products at CBER, presented on data to support a COVID-19 vaccine EUA, highlighting that there is a 2-month minimum follow-up for vaccine participants after completing the full vaccine process. Concerns were raised that the time allotted for monitoring was too short to evaluate safety and effectiveness. It was noted that and issuance of an EUA can risk unblinding a trial, and cause trial participants who are both interested in the emergency COVID-19 vaccine and approved under the EUA to withdraw— resulting in insufficient enrollment in placebo-controlled trials.

The topic of gaining the public's trust in a COVID-19 vaccine was also of top concern among committee members. The CEO of the Reagan-Udall Foundation, Susan Winckler, presented on their COVID-19 Vaccine Confidence Project that assists the FDA with understanding public perception about the vaccine by: identifying themes in the media about the vaccine, hosting listening sessions to gather opinions, addressing concerns and questions, and checking the credibility and relevancy of messages regarding the COVID-19 vaccine. Direct quotes from their listening sessions echo concerns about the speed of the process, distrust of government, distrust of the healthcare system, concerns that politics and economics will be prioritized over science, fears that the vaccine will not work for individuals or their community, and fears based on past experiences.

Many concerns were raised among committee members regarding the inclusion of minority groups, such as American Indians/Alaskan Natives (AI/AN) and African Americans, in trials as well as high-risk groups like those with comorbidities and the elderly. Dr. Hilary Marston, Medical Officer and Policy Advisor for Pandemic Preparedness at National Institute of Health (NIH) presented that trials overseen by NIH have explicit parameters for volunteer enrollment with risk factors. She also stressed that proactive community engagement with minority groups is a top priority for NIH. VRBPAC committee members emphasized that AI/AN and other underserved minority groups are often unrepresented in medicine and are imperative to ensure widespread efficacy in the COVID-19 vaccine.

Learn more: https://www.youtube.com/watch?v=1XTiL9rUpkg&feature=youtu.be