

**Food and Drug Administration
Center for Biologics Evaluation and Research**

**SUMMARY MINUTES
161st VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

October 22, 2020

Committee Members

Hana El Sahly, M.D., Chair +
 Tammy Beckham, D.V.M., Ph.D.
 Archana Chatterjee, M.D., Ph.D.
 CAPT. Amanda Cohn, M.D.
 Hayley Gans, M.D.
 Holly Janes, Ph.D. +
 Michael Kurilla, M.D., Ph.D.
 Myron Levine, M.D., D.T.P.H., F.A.A.P. +
 H. Cody Meissner, M.D.
 Paul Offit, M.D.
 Steven Pergam, M.D., M.P.H.
 Andrea Shane, M.D., M.P.H., M.Sc. +
 Paul Spearman, M.D. +
 Geeta K. Swamy, M.D. +

Industry Representatives

Paula Annunziato, M.D.
 Gregg Sylvester, M.D., M.P.H. <+

Consumer Representative

Sheldon Toubman, J.D. *

Designated Federal Officer (DFO)

Prabhakara Atreya, Ph.D.

Committee Management Specialist(s)

Monique Hill, M.H.A.

* Consumer Representative

+ Not in attendance

< Alternate Industry representative

Temporary Voting Members

Arnold Monto, M.D. (Acting Chair)
 James Hildreth, Sr., Ph.D., M.D.
 Kathryn Holmes, Ph.D.
 Jeannette Lee, Ph.D.
 Michael Nelson, M.D., Ph.D.
 Luigi Notarangelo, M.D.
 Stanley Perlman, M.D., Ph.D.
 David Wentworth, Ph.D.

Speakers and Guest Speakers

Steven Anderson, Ph.D.
 Doran Fink, M.D., Ph.D.
 Marion Gruber, Ph. D.
 Robert Johnson, Ph.D.
 Hilary Marston, M.D., M.P.H.
 L. Clifford McDonald, M.D., F.A.C.P.
 CAPT. Janell Routh, M.D., M.H.S.
 Stephanie Schrag, D. Phil.
 Tom Shimabukuro, M.D., M.P.H., M.B.A.
 Jerry Weir, Ph.D.
 Chrisanne Wilks, Ph.D.
 Susan Winckler, B.S. Pharm., J.D., FAPhA

FDA Participants

Philip Krause, M.D.
 Peter W. Marks, M.D., Ph.D.
 CDR. Valerie Marshall, M.P.H., P.M.P.
 Celia M. Witten, Ph.D., M.D.

These summary minutes for the October 22, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on November 19, 2020.

I certify that I participated in the October 22, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Prabhakara Atreya, Ph.D.
Designated Federal Officer

/s/
Arnold Monto, M.D.
Acting Chair

On October 22, 2020 at 10:00 a.m. Eastern Standard Time (EST), the 161st Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19. No specific application was discussed at this meeting.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that two conflict of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting and the waivers were posted on the FDA website for public disclosure.

Dr. Marion Gruber of FDA provided an introductory presentation titled “Development, Authorization & Licensure of Vaccines to Prevent COVID-19.” This was followed by a presentation by Dr. Cliff McDonald from the Centers for Disease Control and Prevention (CDC) entitled, "Epidemiology, Virology, and Clinical Features of COVID-19." Following Dr. McDonald's presentation was an overview presentation by Dr. Hilary Marston titled ‘COVID-19 Vaccine Development: The Role of the NIH.’ Once her presentation concluded, Dr. Robert Johnson with BARDA presented ‘COVID-19 Vaccine Development Portfolio.’

After a 10-minute break, Dr. Tom Shimabukuro and Dr. Stephanie Schrag with CDC gave a joint presentation on “CDC plans for Vaccine Safety and Effectiveness monitoring & evaluation during future EUA use and post licensure.” Following their presentation, Dr. Steven Anderson with the FDA presented on ‘CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness. Then CAPT. Janell Routh from CDC presented on ‘COVID-19 Vaccine Implementation: Operational aspects of COVID-19 vaccine distribution and tracking.’

After a 30-minute lunch break, the presentations continued, resuming with ‘COVID-19 Vaccine Confidence’ presented by Ms. Susan Winckler and Dr. Wilks, both with the Reagan-Udall Foundation. Dr. Weir with FDA then presented ‘Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Chemistry, Manufacturing, and Controls (CMC) Considerations.’ The last Agency presentation in the afternoon was by Dr. Doran Fink with FDA

titled ‘Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Clinical Considerations.’

After the presentations concluded, a 10-minute break was held, followed by the Open Public Hearing (OPH) session, held for 90 min during which 26 public pre-registered speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website. Following the OPH session, the Committee proceeded with discussions and recommendations. There were three discussion items presented to the Committee:

1) Please discuss FDA’s approach to safety and effectiveness data as outlined in the respective guidance documents.

In general, the VRBPAC endorsed FDA’s approach and recommendations to safety and effectiveness data to support a biologic license application and emergency use authorization as outlined in the respective guidance documents. Some committee members expressed concerns about the median 2 months follow up for safety and effectiveness as stated in the respective guidance, with many indicating that this should be lengthened, and none expressing a recommendation to shorten it. The consensus thus was that a median follow-up of 2 month should be considered to be the minimum follow-up period with recommendation for longer follow-up for both safety and efficacy if feasible. There was discussion regarding the primary clinical trial endpoint, i.e., COVID-19 disease of any severity. Some committee members felt that asymptomatic infection should be followed, given its role in transmission, while other committee members expressed concern that this endpoint may allow a determination of vaccine effectiveness against mild, but not severe disease. FDA stressed the importance of extended follow-up of clinical trial participants even after pre-specified success criteria for vaccine effectiveness would be met, in order to evaluate effectiveness against severe disease. Some committee members expressed concerns about underrepresentation of certain ethnic and racial groups in currently ongoing clinical trials even though the guidance documents encouraged enrollment of diverse racial and ethnic subgroups. Some committee members expressed concerns about the potential use of immune-bridging to support vaccine effectiveness in pediatric populations.

2) Please discuss considerations for continuation of blinded Phase 3 clinical trials if an EUA has been issued for an investigational COVID-19 vaccine.

EUA issuance for a COVID 19 vaccine could present with challenges to preserve the blinded follow-up of Phase 3 clinical trial participants and therefore, interfere with the ability to gather safety and efficacy data needed to support the approval of the product. VRBPAC discussed the challenges of preserving the blind and there was general consensus that efforts should be made to keep the blinded follow-up of Phase 3 clinical trial for as long as feasible. VRBPAC will need to weigh in on this topic again in case an EUA request is submitted for a particular vaccine product.

- 3) Please discuss studies following licensure and/or issuance of an EUA for COVID-19 vaccines to:
 - a. Further evaluate safety, effectiveness and immune markers of protection
 - b. Evaluate the safety and effectiveness in specific populations

VRBPAC members endorsed the importance of additional studies to further evaluate safety, effectiveness of the vaccine after EUA issuance and/or licensure and underscored the need to evaluate the safety and effectiveness of COVID-19 vaccines in specific populations.

The meeting was then adjourned on October 22, 2020 at 6:45 PM EST.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

[YouTube channel](#)