

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

**SUMMARY MINUTES
168th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

September 30, 2021

Committee Members

Hana El Sahly, M.D., Chair
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

Jay Portnoy, M.D. * (Acting)

Designated Federal Officer's (DFO)

Kathleen Hayes, M.P.H.

Committee Management Specialist

Monique Hill, M.H.A.

* Consumer Representative

+ Not in attendance

< Alternate Industry representative

Temporary Non-Voting Member

David Wentworth, Ph.D. (Speaker, Topic II)

FDA Participants

Anissa Cheung, M.S.c. (Speaker, Topic II)
Celia M. Witten, Ph.D., M.D.
Jay Slater, M.D. (Speaker, Topic I)
Marion Gruber, Ph.D.
Monica Young, Ph.D. (Speaker, Topic I)
Philip Krause, M.D.
Peter W. Marks, M.D., Ph.D.
Valerie Marshall, M.P.H, P.M.P.
Willie Vann, Ph.D. (Speaker, Topic I)

These summary minutes for the September 30, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on 10/15/2021.

I certify that I participated in the September 30, 2021 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 OfficerChair

/s/
Hana El Sahly, M.D.
Chair

On September 30, 2021 at 8:30 a.m. Eastern Standard Time (EST), the 168th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to hear an overview of the research programs in the Laboratory of Bacterial Polysaccharides (LBP), Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) and, under Topic II, to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2022 southern hemisphere influenza season.

Dr. Hana El Sahly, the VRBPAC 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 for Topic I into the public record. It was stated that no conflict of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting.

Dr. Monica Young, Senior Advisor to the Associate Director Research, Center for Biologics Evaluation and Research (CBER), FDA provided an overview of the research and the site visit process with a presentation titled "Overview of CBER Research Programs." Dr. Jay Slater, Division Director of the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review, CBER, FDA then provided an Office and Division overview presentation titled "Office of Vaccines Research and Review, Division of Bacterial, Parasitic and Allergenic Products." This was followed by a presentation by Dr. Willie Vann, Chief of the Laboratory of Bacterial Polysaccharides (LBP), DBPAP, OVRR titled "Description of the Laboratory of Bacterial Polysaccharides." Following their presentations, the Committee was released for a 10-minute break. After the break, the first Open Public Hearing session was announced, however, there were no public speakers pre-registered for this portion of the meeting. Therefore, the Committee immediately proceeded with the closed session for the Site Visit report discussions followed by a vote. Following the vote for Topic I, the Committee was then released for a 35-minute lunch break.

Following the lunch break, the Committee proceeded to Topic II, to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2022 southern hemisphere influenza season. After the second COI statement was read by the DFO, the presentations began with Anissa Cheung, Regulatory Coordinator with the Division of Viral Products (DVP), OVRR, who provided an introductory presentation titled "Influenza Virus Vaccine Strain Selection -2022 Southern Hemisphere." This was followed by a presentation by

Dr. David Wentworth with the Centers for Disease Control and Prevention (CDC) titled, "Information for the Vaccine and Related Biological Products Advisory Committee, CBER, FDA: Global Influenza Virus Surveillance and Characterization." After Dr. Wentworth's presentation, the Committee was then released for a 10-minute break. Once the Committee returned from break, the second Open Public Hearing session was announced, however, there were no public speakers pre-registered for this portion of the meeting. Therefore, the Committee immediately proceeded with the discussion and voting portion of the meeting for Topic II.

There were 2 (two) voting questions presented to the Committee for Topic II:

1. For the composition of egg-based trivalent 2022 SH formulations of influenza vaccines, does the committee recommend:
 - A. Inclusion of an A/Victoria/2570/2019 (H1N1)pdm09-like virus
 - B. Inclusion of an A/Darwin/9/2021 (H3N2)-like virus
 - C. Inclusion of a B/Austria/1359417/2021-like virus (B/Victoria lineage)

For question 1, the Committee voting results are as follows: 14 Yes, 0 No, 0 Abstain

2. For quadrivalent 2022 SH formulations of influenza vaccines, does the committee recommend:
 - A. Inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine

For question 2, the Committee voting results are as follows: 14 Yes, 0 No, 0 Abstain

Following the vote, the Committee members provided rationale for their vote and/or any final remarks. Dr. El Sahly then handed the meeting over to the DFO who adjourned the meeting on September 30, 2021 at 2:00 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: <https://youtu.be/VeknygU5MKM>