

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

**SUMMARY MINUTES
171st VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

March 3, 2022

Committee Members

Hana El Sahly, M.D., Chair
Hayley Altman-Gans, M.D.+
Adam Berger, Ph.D.
Henry Bernstein, D.O. MHCM
Archana Chatterjee, M.D., Ph.D.
CAPT. Amanda Cohn, M.D.
Holly Janes, Ph.D.
CAPT. David Kim, M.D., M.S. M.H.A.
Arnold Monto, M.D.
Paul Offit, M.D.
Steven Pergam, M.D. M.PH.+
Eric Rubin, M.D.+
Andrea Shane, M.D., M.P.H., M.Sc.
Geeta K. Swamy, M. D.+

Industry Representatives

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

Consumer Representative

Jay Portnoy, M.D.

Designated Federal Officers (DFO)

Prabhakara Atreya, Ph.D.
Christina Vert, M.S.

Committee Management Specialist(s)

Lisa Wheeler
Joanne Lipkind, M.S.

* Consumer Representative

+ Not in attendance

< Alternate Industry representative

Temporary Voting and Non-Voting Members

COL Douglas Badzik, M.D. M.PH.
David Wentworth, Ph.D. (TNVM)

Speakers and Guest Speakers

CAPT Lisa Grohskopf, M.D., M.P.H. – CDC
David Wentworth, Ph.D.- CDC
Jerry Weir, Ph.D. - FDA
LCDR. Courtney Gustin, Dr.PH. M.S.- DoD
Manju Joshi, Ph.D. - FDA
Beverly Taylor, Ph.D. – Seqirus

FDA Participants

Peter W. Marks, M.D., Ph.D.
Celia M. Witten, Ph.D., M.D.
Doran Fink, M.D., Ph.D.
Robin Levis, Ph.D.
Zhiping Ye, M.D., Ph.D.
Anissa Cheung, M.S.

These summary minutes for the March 3, 2022 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on 22 March 2022.

I certify that I participated in the March 3, 2022 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
(DFO)

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

On March 3, 2022 at 9:00 a.m. Eastern Standard Time (EST), the 171st Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2022 – 2023 influenza season.

Dr. 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 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. Jerry Weir of FDA provided an introductory presentation titled “Influenza Virus Vaccine Strain Selection 2022-2023 Northern Hemisphere.” This was followed by a presentation by Dr. Lisa Grohskopf with the Centers for Disease Control and Prevention (CDC) titled “Influenza Activity and VE Update.” Dr. David Wentworth, also with the CDC, then gave the presentation “Global Influenza Virus Surveillance and Characterization.” Following this presentation, the Committee was released for a 10-minute break. After the break, LCDR. Courtney Gustin with the Department of Defense (DoD) presented “DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness Report.” Following her presentation, Dr. Manju Joshi with the FDA presented, “Candidate Vaccine Strains & Potency Reagents: 2022-2023 Northern Hemisphere Influenza Season.” The Manufacturers’ Representative, Dr. Beverly Taylor with Seqirus, then shared Influenza Vaccine Manufacturing: Industry Perspective for 2021-22 Northern Hemisphere Influenza Vaccine Supply.

After a 45-minute lunch break, the 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 discussions followed by voting for the Topic.

There were 4 (four) voting questions presented to the Committee for the Topic:

Question 1) For the influenza A (H1N1) component of the 2022-2023 influenza virus vaccines in the U.S., does the committee recommend:

- an A/Victoria/2570/2019 (H1N1) pdm09-like virus (Egg-based Vaccines)
- an A/Wisconsin/588/2019 (H1N1) pdm09-like virus (Cell- or Recombinant-based Vaccines)

For question 1, the Committee voting results are as follows: 11 Yes, 0 No, 0 Abstain, 1 NP (Not Present)

Question 2) For the influenza A (H3N2) component of the 2022-2023 influenza virus vaccine in the U.S., does the committee recommend:

- an A/Darwin/9/2021 (H3N2)-like virus (Egg-based Vaccines)
- an A/Darwin/6/2021 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)

For question 2, the Committee voting results are as follows: 11 Yes, 0 No, 0 Abstain, 1 NP (Not Present)

Question 3) For the influenza B component of the 2022-2023 trivalent and quadrivalent influenza virus vaccines in the U.S., does the committee recommend inclusion of a B/Austria/1359417/2021-like virus (B/Victoria lineage)

For question 3, the Committee voting results are as follows: 12 Yes, 0 No, 0 Abstain

Question 4) For quadrivalent 2022-2023 influenza vaccines in the U.S., does the committee recommend inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine

For question 4, the Committee voting results are follows: 12 Yes, 0 No, 0 Abstain

Following the vote, the Committee members provided the rationale for their vote and/or any final remarks. Dr. El Sahly then handed the meeting over to the DFO who adjourned the meeting at 2:30 PM EST on March 3, 2022.

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:** <https://youtu.be/7fIEUdmn3AU>