Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
184th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 5, 2024

Committee Members
Hana El Sahly, M.D., Chair
Adam Berger, Ph.D.
Andrea Shane, M.D., M.P.H., M.Sc.
Archana Chatterjee, M.D., Ph.D.
Arnold Monto, M.D.
Eric Rubin, M.D. Ph.D.+
Henry Bernstein, D.O. MHCM, FAAP
Hayley Gans, M.D.
Jay Portnoy, M.D.
Holly Janes, Ph.D.
Paul Offit, M.D.
CAPT. Sarah Meyer, M.D., M.P.H.
Stanley Perlman, M.D., Ph.D.
Steven Pergam, M.D., M.P.H.

Industry Representatives
Luis Jódar, Ph.D. ***

Consumer Representative
Jay Portnoy, M.D.*

Designated Federal Officers (DFO)
Sussan Paydar, Ph.D.
Prabhakara Atreya, Ph.D.
Valerie Vashio, BPharm, RPh, RAC

Committee Management Staff
Joanne Lipkind
Kathleen Heyes
Lisa Johnson

Temporary Non-Voting Member
Rebecca Garten Kondor, Ph.D.

Speakers and Guest Speakers
Anthony Fries, Ph.D. - DoD
David Greenberg, M.D. - Sanofi
Jerry Weir, Ph.D. - FDA
Lisa Grohskopf, M.D., M.P.H, - CDC
Rebecca Garten Kondor, Ph.D. - CDC

FDA Participants
Peter Marks, M.D., Ph.D.
David C. Kaslow, M.D.
Jerry Weir, Ph.D. (Speaker)
Sudhakar Agnihothram, B. Pharm., Ph.D.
Zhiping Ye, M.D., Ph.D.
Manju Joshi, Ph.D. (Speaker)

+Not Attending
*Consumer Representative
***Industry Representative

These summary minutes for the March 5, 2024, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on April 8, 2024.

I certify that I participated in the March 5, 2024, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Sussan Paydar, Ph.D.
Designated Federal Officer

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Hana El Sahly, M.D.
Chair

On March 5, 2024, at 9:00 a.m. Eastern Daylight Time (EDT), the 184th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2024 – 2025 influenza season.

Dr. Hana El Sahly, the Chair, called the meeting to order. The DFO, Dr. Sussan Paydar made administrative remarks, conducted roll call, and invited the committee members to introduce themselves. She read the Conflict of Interest (COI) statement for the public record.

The meeting began with a 10-minute FDA Introduction by Dr. Jerry Weir, Director, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER) followed by a 5-minute Q&A.

Next Dr. El Sahly called upon Dr. Lisa Grohskopf from Centers for Disease Control and Prevention (CDC) to speak on U.S. Surveillance. The talk was followed by a 5-minute Q&A.

At 10:04 a.m. EDT, Dr. Hana El Sahly called upon Dr. Rebecca Kondor from WHO Collaborating Center for Surveillance, CDC, who gave a 60-minute presentation on "Global Influenza Virus Surveillance and Characterization" followed by a 25-minute Q&A.

The committee took an approximately 10-minute break, reconvening at 11:35 a.m. EDT for a 30-minute session, titled "DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness" by Dr. Anthony Fries. The talk was followed by a 3-minute Q&A.

Dr. Manju Joshi from CBER gave a 15-minute presentation on "Candidate Vaccine Strains and Potency Reagents" followed by a 25-minute presentation from the Industry Representative, Dr. David Greenberg, titled "Comments from Manufacturer Representative". The talk was followed by a 5-minute Q&A.

The Committee then took a 45-minute lunch break, reconvening at 1:30 p.m. EDT for the Open Public Hearing session. The Chair, Dr. Hana El Sahly, read the Chair's Conflict of Interest statement. The floor was then assigned to Dr. Sussan Paydar who provided further OPH

instructions. Two participants made 5-minute remarks, one of whom made a PowerPoint presentation. After the OPH session concluded, Dr. Sussan Paydar returned the floor to Dr. El Sahly to begin the next session. The following three voting questions were discussed for approximately 6 minutes before the meeting was handed over to Dr. Sussan Paydar to conduct the voting session.

(1) Does the committee recommend a trivalent 2024-2025 formulation for egg-based influenza virus vaccines in the U.S. that contains the following virus strains:

- An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- An A/Thailand/8/2022 (H3N2)-like virus; and
- A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

(2) Does the committee recommend a trivalent 2024-2025 formulation for cell-and recombinant-based influenza vaccines in the U.S. that contains the following virus strains:

- An A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- An A/Massachusetts/18/2022 (H3N2)-like virus; and
- A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

(3) For U.S.-licensed quadrivalent influenza vaccines intended for ex-U.S. distribution, does the committee recommend inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine

Dr. El Sahly read aloud each of the Voting Questions for the public record before handing the meeting over to Dr. Paydar to conduct the voting sessions. The voting sessions were held consecutively.

The following three voting questions were presented to the Committee of 13 voting members:

Voting Question #1:
Does the committee recommend a trivalent 2024-2025 formulation for egg-based influenza virus vaccines in the U.S. that contains the following virus strains:

- An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- An A/Thailand/8/2022 (H3N2)-like virus; and
- A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

The voting results were as follows: 13 Yes, 0 No, 0 Abstain

Voting Question #2:
Does the committee recommend a trivalent 2024-2025 formulation for cell-and recombinant-based influenza vaccines in the U.S. that contains the following virus strains:

- An A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- An A/Massachusetts/18/2022 (H3N2)-like virus; and
- A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

The voting results were as follows: 13 Yes, 0 No, 0 Abstain

Voting Question #3:
For U.S.-licensed quadrivalent influenza vaccines intended for ex-U.S. distribution, does the committee recommend inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine

The voting results were as follows: 13 Yes, 0 No, 0 Abstain

Meeting Summary:
There was general agreement among the committee members on transitioning to the trivalent influenza vaccines [egg-and cell-based] only for use in the U.S. starting in the 2024-2025 respiratory virus season, and U.S.-licensed quadrivalent vaccines for ex-U.S. distribution purposes. There was also a general agreement among the committee members that the data presented was informative and convincing of the need to change the H3 components and to maintain the currently recommended H1 and B components.

Following the voting session, Dr. Hana El Sahly asked members for their voting explanations. Dr. El Sahly then asked Dr. David Kaslow for closing remarks.

Dr. David Kaslow thanked the VRBPAC, DSAC and the technical staff for conducting a flawless virtual meeting. He further noted that VRBPAC's "call to action" for excluding the B Yamagata component from quadrivalent vaccines was well received and acted upon by FDA and other relevant stakeholders resulting in a clear recommendation for trivalent influenza vaccines only for use in the U.S, and is a 'case study' on the impact of VRBPAC resulting in timely switch to use of trivalent vaccines only starting 2024-2025 respiratory virus season in the U.S.

The meeting was then handed over to Dr. El Sahly followed by Dr. Paydar who officially adjourned the meeting at 2:32 p.m. EDT on March 5, 2024.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:
Vaccines and Related Biological Products Advisory Committee March 5, 2024 Meeting Announcement - 03/05/2024 | FDA