Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
180th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 7, 2023

Committee Members
Hana El Sahly, M.D., Chair
Adam Berger, Ph.D.
CAPT. Amanda Cohn, M.D.
Andrea Shane, M.D., M.P.H., M.Sc.+
Archana Chatterjee, M.D., Ph.D.
Arnold Monto, M.D.
David Kim, M.D. M.S. M.H.A.+
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.
Stanley Perlman, M.D., Ph.D.
Steven Pergam, M.D., M.P.H.

Industry Representatives
Paula Annunziato, M.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
Karen Thomas
Lisa Johnson

Temporary Voting Member
Douglas Badzik, M.D., M.P.H

Temporary Non-Voting Member
David Wentworth, Ph.D.

Speakers and Guest Speakers
Jerry Weir, Ph.D. - FDA
David Wentworth, Ph.D. - CDC
Anthony Fries, Ph.D. - DoD
Lisa Grohskopf, M.D., M.P.H. - CDC
Elisabeth Neumeier, D.V.M. - GSK

FDA Participants
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 7, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on March 31st, 2023.

I certify that I participated in the March 7, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

--------S-------
_____

Sussan Paydar, Ph.D.
Designated Federal Officer

--------S-------
_____

Hana El Sahly, M.D.
Chair

On March 7, 2023, at 9:00 a.m. Eastern Standard Time (EST), the 180th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2023 – 2024 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 kicked off 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. Dr. Lisa Grohskopf from Centers for Disease Control and Prevention (CDC) presented a 20-minute talk titled "U.S. Surveillance" followed by a 5-minute Q&A.

The guest speaker and Temporary Non-Voting Member was Dr. David Wentworth, Director, WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza, at CDC. Dr. Wentworth gave a 60-minute presentation on "Global Influenza Virus Surveillance and Characterization" followed by a 10-minute Q&A.

The committee was given a 10-minute break before reconvening for the presentation by the next guest speaker, Dr. Anthony Fries, DoD Global Respiratory Pathogen Surveillance Program Lead, United States Air Force School of Aerospace Medicine. He gave a 20-minute presentation titled "DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness" followed by a 5-minute Q&A session.

Dr. Manju Joshi, Lead Biologist, Office of Compliance and Biologics Quality, CBER gave a 20-minute presentation titled "Candidate Vaccine Strains and Potency Reagents" followed by a 5-Minute Q&A.

Next Dr. Elisabeth Neumeier, Director, Technical Life Cycle Management Influenza, GSK gave a 20-minute presentation titled "Comments from Manufacturer Representative" followed by a 5-minute Q&A before the Committee was released for a 40-lunch break.

The Open Public Hearing (OPH) Session began at 1:30PM EST. Ms. Valerie Vashio, the alternate DFO conducted the OPH session with one OPH participant before handing over the meeting to Dr. El Sahly to begin the Committee Discussion of the 4 voting questions.

After thorough discussion by the committee, Dr. El Sahly read aloud each of the Voting Question for the public record before handing the meeting over to Dr. Paydar to conduct the voting session. Four consecutive voting sessions were held.

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

Voting Question #1:
For the influenza A (H1N1) component of the 2023-2024 influenza virus vaccines in the U.S., does the committee recommend:

- **an A/Victoria/4897/2022 (H1N1)pdm09-like virus (Egg-based Vaccines)**
- **an A/Wisconsin/67/2019 (H1N1)pdm09-like virus (Cell-or Recombinant-based Vaccines)**

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

Voting Question #2:
For the influenza A (H3N2) component of the 2023-2024 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)**

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

Voting Question #3:
For the influenza B component of the 2023-2024 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)

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

Voting Question #4:
For quadrivalent 2023-2024 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

The voting results were as follows: 7 Yes, 2 No, 4 Abstain

Dr. Weir announced a typographical error in the Voting Question #1 regarding the second bullet. He announced that "an A/Wisconsin/67/**2019**" should be replaced with "an A/Wisconsin/67/**2022"**. This was read aloud to the Committee. No votes were changed because of this correction.
The overall committee votes remained 13 unanimous "yes".

Afterwards, Dr. El Sahly asked each of the Committee Members to present their justifications for their choice of votes they had cast for the voting questions. Majority of the comments made by committee were on Voting Question #4.

Discussion Summary: There was general agreement among the committee members that the data presented was informative and convincing for the need to change the H1 components and to maintain the currently recommended H3 and B Victoria vaccine components. Committee members discussed the recommendation for a B Yamagata component for a quadrivalent influenza vaccine due to the absence of detectable B Yamagata viruses worldwide over the past 3 years. The majority of the committee agreed with the WHO recommendation to continue to include such a component in quadrivalent vaccines for the current North Hemisphere 2023 – 2024 influenza season because of the uncertainty as to whether the B Yamagata virus lineage was truly extinct; however, committee members noted that this issue would require further discussion at future VRBPAC influenza strain composition meetings.

Following the voting explanation session, Dr. El Sahly handed the meeting to Dr. Paydar who officially adjourned the meeting at 3:27 PM ET on March 7, 2023.

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 7, 2023 Meeting Announcement - 03/07/2023 | FDA