Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
183rd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 5, 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
Lisa Johnson

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

Speakers and Guest Speakers
Jerry Weir, Ph.D. - FDA
David Wentworth, Ph.D. - CDC
David Greenberg, M.D. - Sanofi

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

+Not Attending
*Consumer Representative
***Industry Representative

These summary minutes for the October 5, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on October 25, 2023.

I certify that I participated in the October 5, 2023, 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 October 5, 2023, at 8:30 a.m. Eastern Daylight Time (EDT), the 183rd meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss and make recommendations on the Strain Selection for the Influenza Virus Vaccines for the 2024 Southern Hemisphere 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 started 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. In his introduction, Dr. Weir thanked Dr. David Wentworth for his contributions to VRBPAC over the years and for his many presentations as the Director of WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza, at CDC. He acknowledged that today would be Dr. Wentworth's last presentation in his current capacity as he would be transitioning to his new position at CDC as the Director of Coronaviruses and Other Respiratory Viruses Division.

Next Dr. El Sahly called upon Dr. Wentworth, who gave a 60-minute presentation on "Global Influenza Virus Surveillance and Characterization" followed by a 30-minute Q&A.

The committee was then given a 10-minute break before reconvening for the next 45-minute session, titled "Challenges and Opportunities for Vaccine Strain Composition with the Reduced Public Health Threat from Influenza B/Yamagata Lineage Virus". The first 15-minute presentation titled "Comments from Manufacturers Representative" was given by Dr. Greenberg, Global Senior Expert Medical Strategy, Vaccines, Sanofi. Following this presentation, Dr. Weir made a 15-minute presentation titled "FDA Perspective". The talks were followed by a 15-minute Q&A.

The Open Public Hearing (OPH) Session began at 11:20 a.m. EDT. However, since there were no pre-registered OPH speakers, Dr. El Sahly announced that there were no pre-registered OPH speakers and moved to the next item on the agenda, the Committee Discussion. The Discussion Topics were as follows:

"Please discuss possible changes to the antigen composition of future seasonal influenza vaccines:

- The advantages versus the disadvantages of retaining the B/Yamagata lineage component in the quadrivalent influenza vaccine
- The timing for possible removal of the B/Yamagata lineage component from the current quadrivalent formulation
- The opportunities and challenges for alternative vaccine composition formulations and the data needed to support such changes"

After a thorough 70-minute 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. Three consecutive voting sessions were held.

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

Voting Question #1:
Does the committee recommend excluding the B/Yamagata lineage antigen component from quadrivalent influenza vaccines as soon as possible

The voting results were as follows: 12 Yes, 0 No, 0 Abstain

Note: Dr. Perlman was not available to cast his vote during voting on the first voting question.

Voting Question #2:
For the composition of egg-based trivalent 2024 SH formulations of influenza vaccines, does the committee recommend:

- **Inclusion of an A/Victoria/4897/2022 (H1N1) pdm09-like virus;**
- **Inclusion of an A/Thailand/8/2022 (H3N2)-like virus; and**
- **Inclusion of 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 quadrivalent 2024 SH formulations of influenza vaccines, 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

After the voting process was completed, Dr. El Sahly invited the Committee Members to explain their choice of votes they had cast for the voting questions.

Meeting Summary:

There was a general agreement among the committee members that the data on global surveillance was informative and convincing for the need to change the Influenza A [H1 and H3 antigens] components of the vaccine, while maintaining the current B/Victoria lineage component for the trivalent vaccines. The committee agreed with the WHO recommendation on the B/Yamagata lineage for inclusion in quadrivalent influenza vaccines for the Southern Hemisphere Influenza 2024 season, primarily to avoid any disruption of vaccine supply. The committee also strongly supported the opinion of the WHO influenza vaccine composition advisory committee to exclude the B/Yamagata lineage antigen component from quadrivalent influenza vaccines as soon as possible. VRBPAC committee members emphasized the importance of setting firm timelines for implementing the exclusion of B/Yamagata antigen from quadrivalent influenza vaccines for the Northern Hemisphere 2024-2025 Influenza season. There was general agreement that messaging and communication would be important elements related to the removal of the B/Yamagata component from the quadrivalent vaccine. The committee also urged FDA and sponsors to consider novel approaches to enable licensure of quadrivalent vaccines containing novel formulations.

Following the voting explanation session, Dr. El Sahly asked Dr. Weir for his final comments. Dr. Weir made a few comments regarding the overall impression he had received from the Committee and thanked Dr. Wentworth once again for his contributions. The meeting was then handed over to Dr. Paydar who officially adjourned the meeting at 1:20 p.m. EDT on October 5, 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 October 5, 2023 Meeting Announcement - 10/05/2023 | FDA