Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
177th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 6, 2022

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 Altman-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.
Christina Vert, M.S.

Committee Management Staff
Joanne Lipkind
Karen Thomas
LaShawn Marks

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

Speakers and Guest Speakers
Jerry Weir, Ph.D. - FDA Speaker
Dr. David Wentworth, Ph.D. - CDC Speaker

FDA Participants
Peter W. Marks, M.D., Ph.D.
Jerry Weir, Ph.D.

+Not Attending
*Consumer Representative
***Industry Representative

These summary minutes for the October 6, 2022, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on October 14 , 2022.

I certify that I participated in the October 6, 2022, 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 6, 2022, at 8:30 a.m. Eastern Standard Time (EST), the 177th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss the Strain Selection for the Influenza Virus Vaccines for the 2023 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 kicked off with a 10-minute presentation by Dr. Jerry Weir, Director, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER), FDA. The presentation was titled "Influenza Virus Vaccine Strain Selection – 2023 Southern Hemisphere" and was 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, and Chief, Virology Surveillance and Diagnosis Branch, Influenza Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention. Dr. Wentworth made a 60-minute presentation on "Global Influenza Virus Surveillance and Characterization" followed by a 15-minute Q & A.

The committee was given a 10-minute break before reconvening for the Open Public Hearing (OPH) Session. However, since there were no registered speakers for the OPH session, Dr. El Sahly asked that the Committee begin the next session, the Committee Discussion.

After Committee Discussion, voting sessions were held for 2 Voting questions and Vote Explanation. The following two voting questions were presented to the Committee of 14 voting members:

Voting Question #1:
1. For the composition of egg-based trivalent 2023 SH formulations of influenza vaccines, does the committee recommend:

A. Inclusion of an A/Sydney/5/2021 (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)

The voting results were as follows: 14 Yes, 0 No, 0 Abstain

Voting Question #2:
2. For quadrivalent 2023 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

The voting results were as follows: 12 Yes, 2 No, 2 Abstain

Discussion Summary: During the Discussion period, the committee was asked to provide input on the recommendation made by the WHO on 9/23/2022 to update the strain composition for the upcoming Southern Hemisphere 2023 influenza season. There was general agreement among the committee members that the data presented by Dr. Wentworth was informative and convincing for the need to change the H1 component of the vaccine and to maintain the currently recommended H3 and B Victoria vaccine components for trivalent vaccines. There was an interesting discussion among the committee members regarding the recommendation for a B Yamagata component for a quadrivalent influenza vaccine due to the almost complete 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 time being until the certainty of B Yamagata elimination is established. Committee members noted that this issue would likely require further discussion at future VRBPAC influenza strain composition meetings.

Following the voting discussion, Dr. Marks thanked the Members of the Committee, the speakers, and Advisory Committee staff. The meeting was then adjourned by Dr. Paydar on October 6, 2022, at 11:12AM ET.

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 6, 2022 Meeting Announcement - 10/06/2022 | FDA