Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
185th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
June 5, 2024

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

Industry Representatives
Luis Jódar, Ph.D. ***+
Robert Janssen, M.D. **

Consumer Representative
Jay Portnoy, M.D.*+
Randy Hawkins, M.D. (Acting)

Designated Federal Officers (DFO)
Kathleen Hayes, M.P.H.
Prabhakara Atreya, Ph.D.; Director, DSAC

Committee Management Staff
Joanne Lipkind
Lisa Johnson

Temporary Voting Members
Bruce Gellin, M.D.
Randy Hawkins, M.D.
Jeanette Lee, Ph.D.
Ofer Levy, M.D., Ph.D.
H. Cody Meissner, M.D.
Michael Nelson, M.D., Ph.D.
Mark Sawyer, M.D.
Melinda Wharton, M.D.

Speakers and Guest Speakers
Natalie Thornburg, Ph.D. – CDC
Ruth Link-Gelles, Ph.D. -CDC
David Wentworth, Ph.D - WHO
Frances Priddy, M.D., M.P.H - Moderna
Darin Edwards, Ph.D. - Moderna
Kayvon Modjarrad, M.D., Ph.D. - Pfizer
Robert Walker, M.D. – Novavax

FDA Participants
Peter W. Marks, M.D., Ph.D. - Speaker
David C. Kaslow, M.D.
Jerry Weir, Ph.D. - Speaker
Sudhakar Agnihothram, B. Pharm., Ph.D.

+Not Attending
*Consumer Representative
*>Acting Consumer Rep
***Industry Representative

These summary minutes for the June 5, 2024, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on [Insert Date].

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

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Kathleen Hayes, M.P.H.
Designated Federal Officer

Arnold Monto, M.D.
Acting Chair

On June 5, 2024, at 8:30 a.m. Eastern Daylight Time (EDT), the 185th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on the selection of the 2024-2025 Formula for COVID-19 vaccines.

Dr. Arnold Monto, the Acting Chair, called the meeting to order and made introductory remarks. The meeting was then handed over to the DFO, Kathleen Hayes who made administrative remarks, conducted a roll call, and invited the committee members to introduce themselves. She read the Conflict of Interest (COI) statement for the public record.

The FDA Introduction session started at 8:50 a.m. EDT with an introduction and agenda overview presentation by Dr. Jerry Weir, Division of Viral Products Director. A 5-minute Q & A followed.

Dr. Natalie Thornburg from the Center for Disease Control and Prevention (CDC) gave a 25-minute presentation titled "Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants." Dr. Ruth Link-Gelles gave the second 25-minute CDC presentation titled: "Update on COVID-19 Vaccine Effectiveness." A 10-minute Q & A followed to answer several questions from the Committee.

Dr. David Wentworth, Chair of Technical Advisory Group on Coronavirus Vaccines with the World Health Organization (WHO) gave a 35-minute presentation titled: "WHO TAG-CO-VAC May 2024 recommendation on the antigen composition of COVID-19 vaccines". A 10-minute Q&A followed to answer questions from the Committee. The Committee was then recessed for a 10-minute break at 10:50 a.m. EDT.

The Committee reconvened at approximately 11:00 a.m. EDT for three industry presentations, given by Moderna, Pfizer, and Novavax, respectively. Moderna's presenters, Dr. Frances Priddy and Dr. Darin Edwards gave a 20-minute presentation titled "Moderna COVID-19 Vaccines Update."

Pfizer presenter, Dr. Kayvon Modjarrad, gave the next 20-minute presentation titled "2024-2025 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data."

Novavax presenter, Dr. Robert Walker, gave the third 20-minute presentation titled "Novavax Data in Support of 2024-2025 Vaccine Update."

Following the industry guest speaker presentations, Dr. Jerry Weir presented 'FDA Considerations and Recommendation for Changes to COVID-19 Vaccine Formula Composition." The Committee recessed for a 30-minute lunch break.

The Committee reconvened for the Open Public Hearing (OPH) Session at 1:00 p.m. EDT. The Acting Chair, Dr. Monto read the Chair's Conflict of Interest guidance to the registered OPH speakers followed by DFO Kathleen Hayes who provided further OPH instructions. Ten participants made 4-minute remarks.

After the OPH session concluded, Kathleen Hayes returned the floor to Dr. Monto to conduct an additional 20-minute Q & A session in which the Committee Members asked questions related to CDC, FDA, and industry presentations. At 2:20 p.m. EDT the Committee recessed for a 10-minute break.

The meeting reconvened at 2:30 p.m. EDT. The Chair allowed approximately 30 minutes for the Committee to discuss the Voting Question: "For the 2024-2025 Formula of COVID-19 vaccines in the U.S., does the committee recommend a monovalent JN.1-lineage vaccine composition?

At approximately 2:45 p.m. EDT, the Chair, Dr. Monto, asked Kathleen Hayes to conduct the Voting Session. The 16 voting members of the Committee were presented and asked to vote on the following Voting Question:

"For the 2024-2025 Formula of COVID-19 vaccines in the U.S., does the committee recommend a monovalent JN.1-lineage vaccine composition?"

The voting result was displayed as following: 16 Yes, 0 No, 0 Abstain

Kathleen Hayes read the voting results for the public record and then returned the floor to Dr. Monto to ask the Committee for their Vote explanation. Dr. Monto held a brief voting explanation session.

Discussion Summary:

Committee members noted that the data presented clearly supported a monovalent JN.1-lineage for COVID-19 vaccines (2024-2025 Formula). The committee unanimously voted to recommend the selection of a monovalent JN.1-lineage for COVID-19 vaccines (2024-2025 Formula).

Dr. Monto then started the next session to discuss the one Discussion Topic as listed below:

Based on the evidence presented, please discuss considerations for the selection of a specific JN.1 lineage strain (e.g., JN.1, KP.2, etc.) for COVID-19 vaccines (2024-2025 Formula) to be used in the U.S.

Discussion Summary:

The committee strongly endorsed a monovalent JN.1-lineage COVID-19 vaccine (2024-2025 Formula) and was in overall agreement with JN.1 as the selected lineage strain. The committee emphasized the importance of a strong ACIP recommendation for COVID-19 vaccines (2024-2025 Formula) use to prevent severe disease caused by emerging variants and the need for vaccination with the updated vaccines, especially in unvaccinated individuals. The committee further emphasized the need for presentation of safety data on updated COVID-19 vaccines, a call for a clinically meaningful "correlate of protection/threshold", and a request to consider the 3-step antigen update iteration more than once a year.

At the conclusion of the discussion, Dr. Monto recognized Dr. Marks for his Concluding Remarks. Dr. Marks thanked the Members of the Committee, the speakers, and Advisory Committee staff. Kathleen Hayes then officially adjourned the meeting on June 5, 2024, at 3:26 p.m. EDT.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

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