Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
182nd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
June 15, 2023

Committee Members
Arnold Monto, M.D., Acting Chair
Adam Berger, Ph.D.
Amanda Cohn, M.D.
Andrea Shane, M.D., M.P.H., M.Sc.+
Archana Chatterjee, M.D., Ph.D.
David Kim, M.D. M.S. M.H.A.
Eric Rubin, M.D. Ph.D.
Hana El Sahly, M.D., Chair+
Hayley Gans, M.D.+
Henry Bernstein, D.O. MHCM, FAAP
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.*+
Randy Hawkins, M.D. (Acting)

Designated Federal Officers (DFO)
Sussan Paydar, Ph.D.
Prabhakara Atreya, Ph.D.; Director, DSAC

Committee Management Staff
Joanne Lipkind
Lisa Johnson

Temporary Voting Members
Arthur Reingold, M.D.
Bruce Gellin, M.D., M.PH.
Jeannette Lee, Ph.D.
H. Cody Meissner, M.D.
James Hildreth, Sr. Ph.D., M.D.
Pamela McInnes, DDS, MSc.
Michael Nelson, M.D., Ph.D.
Mark Sawyer, M.D., F.A.A.P.
Melinda Wharton, M.D., M.P.H.
Ofer Levy, M.D., Ph.D.

Speakers and Guest Speakers
Darin Edwards, Ph.D. - Moderna
Filip Dubovsky, M.D. – Novavax
Kanta Subbarao, M.D. MPH - WHO
Kena Swanson, Ph.D. – Pfizer
Natalie Thornburg, Ph.D. – CDC
Rituparna Das, M.D., Ph.D.- Moderna
Ruth Link-Gelles, Ph.D. -CDC

FDA Participants
Peter W. Marks, M.D., Ph.D. - Speaker
David C. Kaslow, M.D. - Speaker
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 15, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 17, 2023.

I certify that I participated in the June 15, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

--- X ---

Sussan Paydar, Ph.D.
Designated Federal Officer

--- X ---

Arnold Monto, M.D.
Acting Chair

On June 15, 2023, at 8:30 a.m. Eastern Standard Time (EDT), the 182nd meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on the selection of strain(s) to be included in the periodic updated COVID-19 vaccines for the 2023-2024 vaccination campaign.

Dr. Arnold Monto, the Acting Chair, called the meeting to order and made introductory remarks. The meeting was then handed over to the DFO, Dr. Sussan Paydar 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 opening remarks by Dr. Peter Marks, CBER Director, who then handed the meeting to Dr. David C. Kaslow, Director of the Office of Vaccines Research and Review (OVRR) in CBER. Dr. Kaslow gave a 10-minute presentation titled "Considerations for Selection of the composition of COVID-19 Vaccines for the 2023-2024 Season". A 5-minute Q & A followed.

Dr. Ruth Link-Gelles from the Center for Disease Control and Prevention (CDC) gave a 25-minute presentation titled "Update on COVID-19 Vaccine Bivalent Effectiveness", which was followed by a 5-minute Q & A. Dr. Natalie Thornburg gave the second 25-minute CDC presentation titled: "Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants". A 10-minute Q & A followed to answer several questions from the Committee.

Dr. Kanta Subbarao, Chair, WHO TAG-Co-VAC, gave the next 25-minute presentation titled: "WHO TAG-CO-VAC May 2023 recommendation on the antigen composition of COVID-19 vaccines". An extended 30-minute Q&A followed to answer numerous questions from the Committee. The Committee recessed for a 10-minute break at 11:05 a.m. EDT.

The Committee reconvened at approximately 11:15 a.m. EDT for three sponsor presentations, given by Moderna, Pfizer, and Novavax, respectively. Moderna's presenters, Dr. Rituparna Das and Dr. Darin Edwards gave a 25-minute sponsor's presentation titled "Moderna COVID-19 Variant Vaccines". A 5-minute Q&A followed their presentations.

Pfizer presenter, Dr. Kena Swanson, gave the next 25-minute sponsor's presentation titled "2023-24 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data". A 5-minute Q & A followed.

Novavax presenter, Dr. Filip Dubovsky, gave the third 25-minute sponsor's presentation titled "Novavax Data in Support of 2023-2024 Vaccine Update." A 5-minute Q & A followed before 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 statement before recognizing Dr. Marks for brief introductory remarks on the OPH session. Dr. Marks requested that OPH presenters avoid derogatory comments towards FDA or the Committee Members. The floor was then assigned to Dr. Paydar who provided further OPH instructions. Fourteen participants made 4-minute remarks, 7 of whom made PowerPoint presentations.

After the OPH session concluded, Dr. Paydar returned the floor to Dr. Monto for the next session. Dr. Monto introduced Dr. Jerry Weir, Director of the Division of Viral Products, OVRR, CBER, FDA who gave a 25-minute presentation on "FDA considerations for potential changes to COVID-19 vaccine strain composition". A 5-minute Q & A followed.

An additional 35-minute Q & A session followed in which the Committee Members asked questions about CDC, FDA, and Sponsor presentations. At 3:15 p.m. EDT the Committee recessed for a 10-minute break.

The meeting reconvened at 3:15 p.m. EDT. The Chair allowed approximately 50 minutes for the Committee to discuss the Voting Question: "For the 2023-2024 Formula of COVID-19 vaccines in the U.S., does the committee recommend a periodic update of the current vaccine composition to a monovalent XBB-lineage?"

Committee members discussed the terminology used in the voting question, including "periodic". At the request of the committee, FDA agreed to remove the word "periodic" in the voting question so as not to presuppose the need for regular updates, as in influenza. The committee asked about FDA's role in supporting the development of COVID-19 vaccines that may offer increased breadth of protection against emerging variants, FDA noted their continuing work with other HHS agencies in support of the development of next-generation COVID-19 vaccines.

At approximately 4:07 p.m. EDT, the Chair, Dr. Monto, asked Dr. Paydar to conduct the Voting Session. The 21 voting members of the Committee were presented and asked to vote on the following Voting Question:

"For the 2023-2024 Formula of COVID-19 vaccines in the U.S., does the committee recommend an update of the current vaccine composition to a monovalent XBB-lineage?"

The vote was: 21 Yes, 0 No, 0 Abstain

Dr. Paydar 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:

The committee unanimously agreed that there is a need to update the vaccine composition from the current bivalent (Original plus Omicron BA.4/BA.5) to a monovalent XBB lineage-derived vaccine candidate. The committee acknowledged FDA's expectation that COVID-19 vaccines would be updated annually unless an ad hoc update was needed for a public health response to a change in the SARS-CoV-2 epidemiology.

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

Based on the evidence and other considerations presented, please discuss selection of a specific XBB lineage (e.g., XBB.1.5 or XBB.1.16 or XBB.2.3) for inclusion in the 2023-2024 Formula of COVID-19 vaccines in the U.S.

Discussion Summary:

The committee agreed that based on the data presented and other practical considerations, including the manufacturing and launch timelines for updated COVID-19 vaccines using different manufacturing platforms, the XBB.1.5 sublineage should be selected for the COVID-19 vaccine 2023-2024 Formula.

At the conclusion of the discussion, Dr. Monto recognized Dr. Paydar who in turn asked Dr. Marks for his Concluding Remarks. Dr. Marks thanked the Members of the Committee, the speakers, and Advisory Committee staff. Dr. Paydar then officially adjourned the meeting on June 15, 2023, at 4:27 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:

Vaccines and Related Biological Products Advisory Committee June 15, 2023 Meeting Announcement - 06/15/2023 | FDA