Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
178th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
January 26, 2023

Committee Members
Stanley Perlman, M.D., Ph.D. Acting 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.
Hana El Sahly, M.D., Chair+
Henry Bernstein, D.O. MHCM, FAAP
Hayley Gans, M.D.
Jay Portnoy, M.D.+
Holly Janes, Ph.D.+
Paul Offit, M.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
Karen Thomas
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.
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.
Wayne Marasco, M.D. Ph.D.

Speakers and Guest Speakers
Antonella Lozito, PharmD – Moderna
Darin Edwards, Ph.D. - Moderna
Filip Dubovsky, M.D. - Novavax
Heather Scobie, Ph.D., M.PH. – CDC
Jefferson Jones, M.D., MPH, FAAP - CDC
John Beigel, M.D. NIH
Kena Swanson, Ph.D. - Pfizer
Nicola Klein, M.D., Ph.D. - Kaiser
Rituparna Das, M.D., Ph.D.- Moderna
Ruth Link-Gelles, Ph.D. -CDC
Tom Shimabukuro, M.D., MPH, MBA - CDC

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

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

These summary minutes for the January 26, 2023, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on February 3, 2023.

I certify that I participated in the January 26, 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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Stanley Perlman, M.D., Ph.D.
Acting Chair

On January 26, 2023, at 8:30 a.m. Eastern Standard Time (EST), the 178th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss future vaccination regimens addressing COVID-19 vaccines.

Dr. Peter Marks, CBER Director, started the meeting with an important announcement on the Chair for today's meeting. He noted that, due to Dr. Monto's unavailability, Dr. Stanley Perlman would be the Acting Chair for today's meeting. Dr. Marks introduced Dr. Perlman and also made remarks in remembrance of Dr. Oveta Fuller, our past TVM member who recently passed away. The meeting was then handed over to Dr. Stanley Perlman, the Acting Chair, who called the meeting to order and made introductory remarks. The DFO, Dr. Sussan Paydar 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 meeting kicked off at 8:55 a.m. with a 5-minute introduction by Dr. Marks in which he introduced Dr. David C. Kaslow as the new Director of the Office of Vaccines Research and Review (OVRR) in CBER. Dr. Kaslow gave a 10-minute presentation titled "Considerations for Simplification of Current COVID-19 Vaccine Use and Periodic Updates to COVID-19 Vaccine Composition", which was followed by 5 minutes of Q&A. Starting at 9:15 a.m. Dr. Heather Scobie 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", which was followed by a 5-minute Q & A. Next was a 40-minute session titled "Update on Original COVID-19 Vaccine and COVID-19 Vaccine Bivalent Effectiveness and Safety". The session began with a 20-minute presentation by Dr. Ruth Link-Gelles followed by a joint XX-minute presentation by Dr. Tom Shimabukuro from CDC and Dr. Nicola Klein from Kaiser Permanente Bernard J. Tyson School of Medicine. Several questions were discussed during the 5-minute Q & A session that followed. Dr. Richard Forshee from FDA then made a presentation titled "Update on Original COVID-19 Vaccine and COVID-19 Vaccine, Bivalent Effectiveness and Safety", which was followed by a 5-minute Q & A. A 20-minute presentation was then given by Dr. John Beigel from NIH titled "Evaluation of Improved Generation COVID-19 Vaccines". A 5-minute Q&A followed to answer several questions before the Committee took a 10-minute break.

The Committee reconvened at approximately 11:30 a.m. EST for a series of presentations given by Moderna, Pfizer, and Novavax, respectively. Moderna presented for 25 minutes, starting with an introduction by Dr. Antonella Lozito titled "Moderna COVID-19 Bivalent Vaccines Primary Series and Booster". Two presentations by Dr. Rituparna Das followed. The first on "Clinical Data with Omicron-Containing mRBA-1273 Bivalent Vaccines", and the second on "Real-world Effectiveness Data". Dr. Darin Edwards then presented "Preclinical results from Authorized and Investigational Multivalent Vaccines". Dr. Das provided the final summary and conclusions on behalf of the Moderna, which was followed by a 5-minute Q & A. The next 25-minute presentation was Dr. Kena Swanson from Pfizer, entitled "Pfizer/BioNTech COVID-19 Variant Vaccines", which was followed by a 5-minute Q & A. Dr. Filip Dubovsky from Novavax made a 25-minute presentation titled "Novavax Vaccine Regimens Addressing COVID-19." A 5-minute Q & A followed before the Committee was released for a 30-minute lunch break.

The Committee reconvened for the Open Public Hearing (OPH) Session at 1:30 pm EST. The Acting Chair, Dr. Perlman read the Chair's Conflict of Interest statement before turning to 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 meeting was then turned over to Dr. Paydar who provided further OPH instructions. Sixteen participants made 3-minute remarks, 8 of whom made PowerPoint Presentations. Four international participants, one each from Canada, Australia, England, and Colombia, presented in the OPH session.

After the OPH session concluded, Dr. Paydar returned the meeting to Dr. Perlman for the next session. Dr. Perlman introduced Dr. 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". The session was followed by a 5-minute Q & A. After a very brief break, Dr. Perlman reconvened the meeting for an additional Q&A session in which Committee members asked questions about presentations from FDA, CDC, and industry firms.

After the additional Q & A session with the presenters, the Committee Discussion and Voting session began with Dr. Kaslow reading the voting question for the Committee. The Chair allowed approximately 25 minutes of discussion by the Committee on the Voting Question before requesting that Dr. Paydar conduct the voting. The following voting question was presented to the Committee of 21 voting members:

***Simplification* of current COVID-19 vaccine use:**

• *Vaccine composition*: Does the committee recommend harmonizing the vaccine strain composition of primary series and booster doses in the U.S. to a single composition, e.g., the composition for all vaccines administered currently would be a bivalent vaccine (Original plus Omicron BA.4/BA.5)?

The voting results were as follows: 21 Yes, 0 No, 0 Abstain

Dr. Paydar read the voting results for the public record and then handed over the meeting to Dr. Perlman to ask the Committee for their Vote explanation. Dr. Perlman called upon each Committee Member in alphabetical order. Several members emphasized that harmonizing the composition of primary series and booster doses is an important step in improving vaccine uptake in all age groups.

Dr. Perlman then started the next session to discuss the two Discussion Topics as listed below:

Discussion Topic 1:
Future periodic vaccination campaigns:
***Simplification* of COVID-19 vaccine use:**
• *Immunization schedule*: Please discuss and provide input on simplifying the immunization schedule to authorize or approve a two-dose series in certain young children, and in older adults and persons with compromised immunity, and only one dose in all other individuals.
The committee agreed in principle that simplification of the immunization schedule was highly desirable and recommended that the simplification be based on the best available evidence.

Discussion topic 2:
***Periodic update* to COVID-19 vaccines:**
• *Vaccine composition:* Please discuss and provide input on the consideration of periodic updates to COVID-19 vaccine composition, including to the currently authorized or approved vaccines to be available for use in the U.S. in the fall of 2023.
The committee agreed that periodic updates to COVID-19 vaccine strain composition would need to be considered annually, if not biannually, and that FDA and VRBPAC need to be prepared for urgent updates if escape variant strains emerge.

At the conclusion of the discussion on both topics, Dr. Perlman handed the meeting over to 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 January 26, 2023, at 5:30 p.m. EST.

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 January 26, 2023 Meeting Announcement - 01/26/2023 | FDA