Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
189th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
May 22, 2025

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.
CAPT Sarah Meyer, M.D.
Flor M. Munoz-Rivas, M.D., M.Sc.+
Michael Nelson, M.D., Ph.D. +
Paul Offit, M.D. +
Stanley Perlman, M.D., Ph.D.
Eric Rubin, M.D., Ph.D

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

Consumer Representative
Jay Portnoy, M.D.*+

Designated Federal Officers (DFO)
Valerie Marshall
Asia Blackwell

Speakers and Guest Speakers
Natalie Thornburg, Ph.D. – CDC
Ruth Link-Gelles, Ph.D. - CDC
Kanta Subbarao, M.B.B.S., M.P.H - Laval University
Spyros Chalkias, M.D. - Moderna
Darin Edwards, Ph.D. - Moderna
Jacqueline Miller, M.D. - Moderna
Kayvon Modjarrad, M.D., Ph.D. - Pfizer
Robert Walker, M.D. – Novavax
Tonya Colpitts, Ph.D. - Novavax

FDA Participants
Vinayak Prasad, M.D., M.P.H. - 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 May 22, 2025, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 16, 2025.

I certify that I participated in the May 22, 2025, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/ /s/

CDR Valerie Marshall, M.P.H., P.M.P. Arnold Monto, M.D.
Designated Federal Officer Acting Chair

On May 22, 2025, at 8:00 a.m. Eastern Standard Time (EST), the 189th 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 2025-2026 Formula for COVID-19 vaccines.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. Next, Dr. Vinayak Prasad, Director of the Center for Biologics Evaluation and Research (CBER) made introductory remarks. The meeting was then handed over to the DFO, Valerie Marshall 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. EST 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 Centers 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 genomics." Dr. Ruth Link-Gelles gave the second 25-minute CDC presentation titled: "Update on COVID-19 Vaccine Effectiveness." A 5-minute Q & A followed to answer several questions from the Committee.

Dr. Kanta Subbarao, Professor, Department of Microbiology and Immunology, Faculty of Medicine, Laval University, gave a 35-minute presentation titled: "TAG-CO-VAC May 2025 recommendation on 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 20-minute break at 10:40 a.m. EST.

The Committee reconvened at approximately 11:00 a.m. EST for three industry presentations, given by Moderna, Pfizer, and Novavax, respectively.

Moderna's presenters, Dr. Spyros Chalkias, Dr. Darin Edwards, and Dr. Jacqueline Miller, gave a 20-minute presentation titled "Moderna COVID-19 Vaccines Update."

Pfizer presenter, Dr. Kayvon Modjarrad, gave the next 20-minute presentation titled "Pfizer/BioNTech COVID-19 Vaccines Update."

Novavax presenters, Dr. Robert Walker, and Dr. Tonya Colpitts, gave the third 20-minute presentation titled "Novavax COVID-19 Vaccines 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 40-minute lunch break.

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

After the OPH session concluded, Valerie Marshall returned the floor to Dr. Monto to conduct an additional 30-minute Q & A session in which the Committee Members asked questions about CDC, FDA, TAG-GO-VAC, and industry presentations.

At approximately 2:45 p.m. EST, Dr. Monto requested that Valerie Marshall conduct the Voting Session. Nine voting members of the Committee were asked to vote on the following Voting Question:

"For the 2025-2026 Formula of COVID-19 vaccines in the U.S., does the Committee recommend a monovalent JN.1-lineage vaccine composition? "Yes," or "No," or "Abstain."

The voting result was as follows: 9 Yes, 0 No, 0 Abstain

Valerie Marshall read the voting results for the public record and then returned the floor to Dr. Monto to ask the Committee to explain their vote. Dr. Monto held a brief voting explanation session.

Discussion Summary:

The committee unanimously recommended a monovalent JN.1-lineage COVID-19 vaccine composition for the 2025–2026 Formula in the U.S., acknowledging JN.1's dominance among circulating variants. Discussion focused on selecting the optimal strain within the JN.1 lineage, with several members supporting LP.8.1 for its slightly broader immunogenicity, while others favored retaining current strains (e.g., JN.1 or KP.2) for implementation and regulatory continuity.

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 JN.1 and/or a specific JN.1-lineage strain for COVID-19 vaccines (2025-2026 Formula) to be used in the U.S.

Discussion Summary:

The committee strongly endorsed a monovalent JN.1-lineage COVID-19 vaccine (2025–2026 Formula) and was in overall agreement with the selection of a JN.1-lineage strain as the basis for updated vaccines. Members discussed the scientific and practical rationale for specific sublineage selection, expressing support for either KP.2 or LP.8.1, while aligning with the recommendation from WHO's TAG-CO-VAC. The committee emphasized the importance of

deploying updated vaccines in a timely manner to mitigate severe outcomes associated with ongoing viral evolution, especially in vulnerable and under-vaccinated populations. The committee further highlighted the need for enhanced communication strategies to increase vaccine uptake, the importance of continued monitoring of viral evolution, and the value of generating and presenting safety data specific to updated COVID-19 vaccines. Members also called for progress toward establishing a clinically meaningful correlate of protection or immunologic threshold and expressed interest in revisiting the vaccine composition update process more than once annually if necessitated by emerging data.

At the conclusion of the discussion, Dr. Monto called on Dr. David Kaslow, Director, Office of Vaccines Research and Review (OVRR)/CBER to provide Concluding Remarks. Dr. Kaslow thanked the Members of the Committee, speakers, and FDA staff.

Valerie Marshall then officially adjourned the meeting on May 22, 2025, at 3:26 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:

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