Food and Drug Administration
Center for Biologics Evaluation and Research
Summary Minutes
190th Vaccines and Related Biological Products Advisory Committee Meeting
October 9, 2025

Committee Members
Hana M. El Sahly, MD (Chairperson)
Adam Berger, PhD +
Henry H. Bernstein, DO, MHCM, FAAP
Archana Chatterjee, MD, PhD+
Anna Durbin, MD
Hayley Gans, MD+
CAPT Sarah Meyer, MD, MPH
Arnold S. Monto, MD
Flor M. Munoz-Rivas, MD MSc+
Michael R. Nelson, MD, PhD+
Saad B. Omer, MBBS, MPH, PhD
Stanley M. Perlman, MD, PhD
Jay M. Portnoy, MD**
Eric J. Rubin, MD, PhD

Industry Representative Member
Temi Folaranmi, MD, MPH, MPP***+

Alternate Industry Representative Member
James Kollar, MD ~

Temporary Voting Members
Amal Assa'ad, MD (Topic II)
Carla Davis, MD (Topic II)
Mark Dykewicz, MD (Topic II)
Paul Greenberger, MD (Topic II)

+Not Attending
** Consumer Representative
*** Industry Representative
~Alternate Industry Representative

Speaker and Guest Speakers
CDC Speaker (Topic I):
Rebecca Kondor, PhD

Guest Speaker (Topic II):
Thomas Platts-Mills, MD

Organizational Speaker (Topic II):
Trena Repp

FDA Participants
Vinayak Prasad, MD MPH
David C. Kaslow, MD (Presenter)
Karin Bok, MS, PhD
Sudhakar Agnihothram, BPharm, PhD
Jerry Weir, PhD
Zhiping Ye, PhD
Ronald Rabin, MD (Presenter)
Michael Brad Strader, MSc, PhD (Presenter)
Sharon Tennant, PhD, MPH

Designated Federal Officer (DFO)
LCDR Cicely Reese, PharmD

These summary minutes for the October 9, 2025, meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) were approved on the 20th of November 2025.

I certify that I participated in the October 9, 2025, meeting of the VRBPAC meeting and that these minutes accurately reflect what transpired.

_/s/_
Cicely Reese, PharmD, LCDR
USPHS, Designated Federal Officer

_/s/_
Hana M. El Sahly, MD
Chairperson

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On October 9, 2025, the 190th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on two separate topics. Under Topic I, the Committee discussed and made recommendations on the strain selection for the influenza virus vaccines for the 2026 Southern Hemisphere influenza season. Under Topic II, the Committee discussed and made recommendations on advancing CBER's allergen standardization program. Given the topics of this meeting, Topic I was determined to be a Particular Matter Involving Specific Parties (PMISP). Topic II was determined to be a Particular Matter of General Applicability (PMGA).

On October 9, 2025, at 8:30 a.m. Eastern Daylight Time (EDT), Dr. Hana El Sahly, Chairperson, called the meeting to order. The DFO, Dr. Cicely Reese, made administrative remarks, conducted roll call, invited the VRBPAC members and consultants to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. There were no conflict-of-interest waivers issued under 18 U.S. Code Section 208 in connection with this meeting.

Dr. Hana El Sahly, Chairperson, convened the Open Public Hearing (OPH) for Topic I of the meeting. Since there were no registered speakers for the OPH, the Chairperson immediately closed the session and moved into presentations to the Committee.

During the open session, the VRBPAC members, consultants, FDA speakers and staff, and invited Guest speakers participated via Zoom web conference.

Dr. David Kaslow, Director, Office of Vaccines Research and Review, provided the Introduction to the VRBPAC Meeting Topics, followed by Questions and Answers (Q &A).

Following Introductory Remarks, FDA and CDC speakers provided presentations entitled:

- Introduction to Seasonal Influenza Vaccine Strain Selection Southern Hemisphere 2026: Jerry Weir, PhD
- CDC: Global Seasonal Influenza Virus Surveillance and Characterization: Rebecca G. Kondor, PhD.

Each of these presentations were followed by Q &A sessions with the Committee.

Immediately following the last Q &A session, the Chairperson allowed a 10-minute break.

When the Committee returned from the break, the Chairperson began the Committee Discussion of the following Topic I voting question presented to the Committee:
Voting Question 1. For the composition of egg-based trivalent 2026 SH formulations of influenza vaccines, does the committee recommend:

- An A/Missouri/11/2025 (H1N1)pdm09-like virus;

- An A/Singapore/GP20238/2024 (H3N2)-like virus; and
- A B/Austria/1359417/2021 (B/Victoria lineage)-like virus

Immediately following Committee Discussion of the voting questions, the Chairperson and DFO invited and led the Committee into the voting session. The vote was Yes: 9 No: 0 Abstain: 0.

Summary of Discussion:
VRBPAC commended CDC's presentation of the comprehensive data generated from global surveillance in support of the selection of the three influenza virus strains for egg-based influenza virus vaccines for the 2026 Southern Hemisphere influenza season. VRBPAC emphasized generation of nonclinical and clinical data to evaluate the role of neuraminidase and the potential inclusion of two H3N2 strains, given the opportunity (due to absence of B/Yamagata-lineage virus) to include an additional strain/antigen in the currently licensed quadrivalent influenza vaccines[1]. VRBPAC noted that the B/Victoria-lineage (i.e., B/Austria/1359417/2021) component has not been updated for several years. A committee member emphasized that recommendation of H3N2 strain for inclusion in Northern Hemisphere influenza vaccines should take the Southern Hemisphere surveillance data into account, which may be supported by certain manufacturing technologies[2] with ability to accelerate manufacturing timelines.

Following the Committee Discussion, Chairperson, Dr. Hana El Sahly, adjourned the meeting for a 30-minute lunch break.

Immediately following the lunch break, at approximately 11:33 a.m. Eastern Daylight Time (EDT), Dr. Hana El Sahly, Chairperson, called Topic II of the meeting to order. The DFO, Dr. Cicely Reese, made administrative remarks, conducted roll call, invited the VRBPAC members and consultants to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. There were no conflict-of-interest waivers issued under 18 U.S. Code Section 208 in connection with this meeting.

Dr. Hana El Sahly, Chairperson, convened the Open Public Hearing (OPH) for Topic II of the meeting. Since there were no registered speakers for the OPH, the Chairperson immediately closed the session and moved into presentations to the Committee.
During the open session, the VRBPAC members, consultants, FDA speakers and staff, and invited Guest speakers participated via Zoom web conference.

Following the invitation, the FDA speakers, Guest Speaker, and Organizational Speaker provided presentations entitled:

- Replacement of Radial Immunodiffusion (RID) Assays of Currently Standardized Extracts

[1] Manufacturers of U.S. approved Quadrivalent Influenza vaccines still retain their license. **N.B.** OVRR did not comment on the proposal to replace the B/Yamagata-lineage with an A/H3N2-lineage in the existing quadrivalent vaccine BLAs
[2] Manufacturing technologies that are based on nucleic acid, cell culture, and recombinant antigen expression

with ELISA or Aptamer-based Enzymatic Assays: Ronald L. Rabin, MD.

- Use of Tandem LC/MS/MS to Measure Potencies of Complex Extracts with Multiple "Major Allergens," and Use of HDM Bodies and Fecal Pellets as Source Materials for HDM Extracts: Ronald L. Rabin, MD and Michael Brad Strader, MSc, PhD.

- Approaches to Allergen Standardization Related to Dust Mites: Thomas Platts-Mills, MD.

- Industry Perspective from the Allergen Products Manufacturers' Association (APMA): Trenna Repp.

Each of FDA and Speaker presentations were followed by Q &A sessions with the Committee.

Immediately following the last Q &A session, the Chairperson allowed a 10-minute break.

When the Committee returned from the break, the Chairperson began the Committee Discussion of the below Topic II voting questions presented to the committee.

Immediately following Committee Discussion of the voting questions, the Chairperson and DFO invited and led the committee into the voting session. The outcome of the voting are noted below:

Voting Question 1: Mass Concentration Measurements
Does measurement of mass concentrations by ELISA of their major allergens provide a scientifically sound approach for expressing and reporting potencies of cat hair and pelt allergen extracts, and of short ragweed pollen allergen extracts?

Yes: 12 No: 0 Abstain: 1

Voting Question 2: CBER's Allergenic Standardization Program
Are the revised assays for cat hair/pelt and ragweed pollen allergen extracts scientifically appropriate templates for expanding CBER's allergenic standardization program to include major food allergens and environmental allergens?

Yes: 11 No: 1 Abstain: 1

Voting Question 3: LC/MS/MS Analytics
Does LC/MS/MS technology, compared with the currently used analytic technology, provide sufficient fit-for-purpose analytical capability for better characterization of complex allergen extracts to improve product quality?

Yes: 8 No: 2 Abstain: 1

Voting Question 4: House Dust Mite (HDM) Source Material
Do the available data support inclusion of both house dust mite (HDM) bodies and fecal pellets as source materials for HDM allergen extracts to more adequately mimic clinically relevant allergen exposure?

Yes: 11 No: 1 Abstain: 1

Summary of Discussion:
The second topic of the 190th VRBPAC meeting focused on advancing CBER's allergen standardization program comprised of four proposed initiatives. The first two initiatives proposed replacement of radial immunodiffusion (RID) assays with modern ELISA and aptamer-based methods for measuring the major allergens Fel d 1 (cat) and Amb a 1 (ragweed). Once these assays are validated, the intent is to change the potency units to mass concentrations, and to use these assays to expand CBER's allergen extract standardization program to include major food environmental allergens. In the third initiative, CBER proposed to characterize complex allergen extracts, such as those from house dust mites and fungi, using LC/MS/MS technology and to adopt this strategy for complex allergen extracts. In the fourth initiative, CBER proposed to use LC/MS/MS data to select source materials for complex extracts, such as including fecal pellets which contain most airborne allergens, in house dust mite extracts. A presentation from an industry representative emphasized concerns about implementation costs, manufacturing complexities, and the need for ring trials before mandatory adoption. The committee voted in favor of all four proposed initiatives advancing CBER's allergen standardization program, emphasizing in their discussion that changes to CBER's allergen standardization program should be linked to clinical outcomes. In addition, the committee advocated for collaboration with academic institutions and professional organizations to confirm that these modernized standardization methods will improve patient diagnostics and therapeutic outcomes.

Following the Committee Discussion, Chairperson, Dr. Hana El Sahly, invited Dr. Kaslow to provide closing remarks.

Following Dr. Kaslow's closing remarks, the Chairperson thanked everyone.
The committee DFO adjourned the meeting on October 9, 2025, at 5:10 p.m. EDT.

Additional meeting information and details may be obtained from the transcript, which may be viewed at:
Vaccines and Related Biological Products Advisory Committee October 9, 2025 Meeting Announcement - 10/9/2025 | FDA.

The recording of the webcast of the meeting may be viewed at:
https://youtube.com/live/UpPFM1bGOog.