Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
187th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 10, 2024

Committee Members
Hana El Sahly, M.D., Chair
Adam Berger, Ph.D.
Andrea Shane, M.D., M.P.H., M.Sc. (topic III only)
Archana Chatterjee, M.D., Ph.D.
Arnold Monto, M.D.
Eric Rubin, M.D. Ph.D.
Henry Bernstein, D.O. MHCM, FAAP
Hayley Gans, M.D.
Holly Janes, Ph.D. +
Michael Nelson, M.D., Ph.D. +
Paul Offit, M.D.
CAPT. Sarah Meyer, M.D., M.P.H.+
Stanley Perlman, M.D., Ph.D.
Steven Pergam, M.D., M.P.H.+

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

Consumer Representative
Jay Portnoy, M.D.*

Designated Federal Officers (DFO)
Kathleen Hayes, MPH
Sussan Paydar, Ph.D.

Committee Management Staff
Joanne Lipkind
Lisa Johnson

Temporary Voting Member
Melinda Wharton, M.D., M.PH.

Speakers and Guest Speakers
Todd Davis, Ph.D., MSPH
Rebecca Garten Kondor, Ph.D.
Christine Oshanksy, Ph.D.

FDA Participants
Peter Marks, M.D., Ph.D.
Karen Elkins, Ph.D. (Speaker)
David C. Kaslow, M.D. (Speaker)
Sudhakar Agnihothram, B. Pharm., Ph.D.
Tod Merkel, Ph.D. (Speaker)
Jerry Weir, Ph.D. (Speaker)
Zhiping Ye, Ph.D. (Speaker)
Keith Peden, Ph.D. (Speaker)
Prabhakara Atreya, Ph.D.

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

These summary minutes for the October 10, 2024, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on November 13, 2024.

I certify that I participated in the October 10, 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, MPH Designated Federal Officer	Hana El Sahly, M.D. Chair

On October 10, 2024, at 8:00 a.m. Eastern Daylight Time (EDT), the 187th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened to discuss three topics. In the morning, for Topic I, the committee met in open session to discuss the Strain Selection for the Influenza Virus Vaccines for the 2025 Southern Hemisphere Influenza Season.

For Topic II, the committee met in open session to discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines.

In the afternoon for Topic III, the committee met in open session to hear an Overview of Research Programs in the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) and the Laboratory of DNA Viruses (LDNAV) in the Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). After the open session was completed, in the latter part of the afternoon, the meeting was closed to the public to permit for committee deliberations disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

Dr. Hana El Sahly, the Chair, called the meeting to order at 8:00 a.m. EDT. The DFO, Kathleen Hayes, made administrative remarks, conducted roll call, and invited the committee members to introduce themselves. She read the Conflict of Interest (COI) statement for the public record.

The meeting began with a 10-minute FDA Introduction by Dr. David Kaslow, Director, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER). Next Dr. El Sahly called upon Dr. Jerry Weir, Director, Division of Viral Products, Center for Biologics Evaluation and Research (CBER), to introduce the seasonal influenza vaccine strain selection southern hemisphere for 2025. The talk was followed by a 5-minute Q&A.

Following this presentation, Dr. El Sahly introduced Dr. Rebecca Kondor from the Centers for Disease Control and Prevention (CDC) to present ‘CDC: Global Seasonal Influenza Virus Surveillance and Characterization,’ that was followed by a 15-minute Q&A.

The committee then took an approximately 10-minute break, reconvening at 9:40 a.m. EDT. There were no registered Open Public Hearing Speakers (OPH) registered for Topic I, so the Committee moved forward with the discussion, recommendations, and voting.

After thorough discussion by the committee, Dr. El Sahly read aloud each of the voting questions for the public record before handing the meeting over to Kathleen Hayes to conduct the voting session.

The following two voting questions were presented to the Committee of 11 voting members:

Voting Question #1:

For the composition of egg-based trivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
Inclusion of an A/Victoria/4897/2022 (H1N1) pdm09-like virus;
Inclusion of an A/Croatia/10136RV/2023 (H3N2)-like virus; and
Inclusion of a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The voting results were as follows: 11 Yes, 0 No, 0 Abstain

Voting Question #2:

For quadrivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
Inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine.

The voting results were as follows: 11 Yes, 0 No, 0 Abstain

Afterwards, Dr. El Sahly asked each of the Committee Members to present their justifications for the votes they had cast for the voting questions.

Discussion Summary:
There was a general agreement among the committee members that the data on global surveillance was informative of influenza viruses and convincing for the need to change the Influenza A [H3 antigen] component of the vaccine, while maintaining the Influenza A [H1 antigen] and the current B/Victoria lineage component for the trivalent vaccines. The committee agreed with the WHO recommendation on the B/Yamagata lineage for inclusion in quadrivalent influenza vaccines for the Southern Hemisphere Influenza 2025 season, primarily to avoid any disruption of vaccine supply and emphasized the need for a global alignment on distribution of trivalent influenza vaccines that exclude B/Yamagata antigen. In response to the committee members inquiry on the projected timeline for global implementation of trivalent influenza vaccines, FDA responded that such implementation would require a concerted effort between global regulatory agencies and the manufacturers, and that may take some time. The committee

further noted that the importance of communicating to the public that the vaccine effectiveness data was derived from vaccine-immune population rather than naïve population.

Following the voting explanation session, Dr. El Sahly handed the meeting to Kathleen Hayes in which Topic I was formally adjourned by the DFO at 10:20 a.m. EDT.

The meeting proceeded on to Topic II discuss Pandemic Preparedness for Highly Pathogenic Avian Influenza Virus Including Considerations for Vaccine Composition for (H5) Vaccines. Dr. El Sahly re-introduced Dr. Weir for a 15-minute presentation titled 'Introduction to Highly Pathogenic Avian Influenza (H5) Virus Vaccines,' followed by a 5-minute Q&A. Dr. El Sahly then introduced Dr. Todd Davis with the CDC to present 'CDC: Highly Pathogenic Avian Influenza A (H5Nx) Virus Surveillance and Characterization in the United States and Globally and Recommendations for Candidate Vaccine Virus Development,' followed by a 10-minute Q&A. The final presenter for Topic II was Dr. Christine Oshansky with the Biomedical Advanced Research and Development Authority (BARDA) who gave a 20-minute presentation 'BARDA's Pandemic Influenza Preparedness and Response Program,' with a 5-minute Q&A.

The Committee was then released for lunch and reconvened at 12:20 p.m. EDT. There were no registered Open Public Hearing Speakers (OPH) registered for Topic II, so the Committee moved forward with discussion. The discussion topics for Topic II included:

1) Please discuss and provide input on the proposed strain change process during the inter-pandemic period.

2) Please discuss whether a change to the current composition of licensed prototype vaccines using the proposed process is needed for preparedness purposes and whether candidate vaccine viruses are available that are appropriate to update currently licensed prototype vaccines.

Discussion Summary:

VRBPAC members generally agreed with implementing the proposed strain change process and collecting the chemistry, manufacturing, and control (CMC), human safety and immunogenicity data from candidate H5 influenza vaccines during the inter-pandemic period. VRBPAC noted that a change to the current composition of the licensed prototype vaccines is rational and needed for preparedness purposes, given the strains represented in the currently licensed prototype vaccines no longer circulate. The committee further opined that the proposed candidate vaccines A/H5N8/Astrakhan and A/H5N1/American Widgeon may be appropriate to update the currently licensed prototype H5N1 vaccines during the current interpandemic period. The committee discussed several other considerations, including genetic changes in avian influenza virus contributing to pathogenicity and increased transmissibility, global surveillance efforts for rapid detection of emerging avian influenza viruses, vaccination for poultry, testing of correlates of protection during the clinical testing of candidate H5 vaccines and the need for implementing innovative manufacturing technologies that can contribute to rapid deployment of strain-matched vaccines early during a pandemic.

Following the discussion session, Dr. El Sahly handed the meeting to Kathleen Hayes, DFO to formally adjourn Topic II at 1:23 p.m. EDT. Following adjournment, the committee was released for a 10-minute break.

At 1:33 p.m. EDT after a 10-minute break, the Committee met in open session to hear an Overview of Research Programs in the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) and the Laboratory of DNA Viruses (LDNAV) in the Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). The VRBPAC Chair called the meeting to order and welcomed everyone, and then handed the meeting over to the DFO for the brief roll call and reading of the Conflict-of-Interest Statement. Dr. Karen Elkins provided an overview of the Site Visit Process and Dr. Merkel provided an overview of research conducted in CBER, OVRR, and DVP followed by 5-minute Q&A.

Next Dr. El Sahly called upon Dr. Zhiping Ye, Chief and Principal Investigator from the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD), OVRR who provided an "Overview of Laboratory of Pediatric & Respiratory Viral Diseases" followed by 5-minute Q&A.

Following Dr. Ye's presentation, Dr. El Sahly called on Dr. Keith Peden, Chief and Principal Investigator from the Laboratory of DNA Viruses (LDNAV), OVRR who provided an 'Overview of Laboratory of DNA Viruses,' followed by 5-minute Q&A.

The presentations were followed by the Open Public Hearing (OPH) Session, however, since there were no pre-registered OPH speakers, Dr. El Sahly announced that there were no pre-registered OPH speakers and concluded the open portion of the meeting at 2:25 p.m. EDT.

The Committee and the CBER senior leadership then moved to the Closed Session for the Site Visit Report discussions.

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 October 10, 2024 Meeting Announcement - 10/10/2024 | FDA