Food and Drug Administration
Center for Biologics Evaluation and Research
Summary Minutes
193rd Vaccines and Related Biological Products Advisory Committee Meeting

**June 18, 2026**

**Committee Members**
**(Voting)**
Adam Berger, PhD
Anna Durbin, MD
Hayley Gans, MD
Flor M. Munoz-Rivas, MD MSc
Michael R. Nelson, MD, PhD+
Saad B. Omer, MBBS, MPH, PhD

**Consumer Representative Member****
**(Non-Voting)**
Jay Portnoy, MD+

**Industry Representative Member**
**(Non-Voting)*****
Temi Folaranmi, MD, MPH, MPP+

**Alternate Industry Representative**
**(Non-Voting)** ~
James Kollar, MD

**Temporary Members**
**(Voting)**
Hana M. El Sahly, MD
Arnold S. Monto, MD (*Acting)
Manisha (Mo) Patel, MD, MS, MBA
Stanley M. Monto, MD, PhD

**Speakers and Guest Speakers**
*(in order of speaking)*
Lisa Grohskopf, MD, MPH- CDC speaker
Richard Webby, PhD

**FDA Participants**
David C. Kaslow, MD (Presenter)
Rachel Zhang, MD
Joseph Kulinski, PhD (Presenter)
Gauri Raval, MD, MPH (Presenter)
Timothy P. Brennan, MD, PhD, MS (Presenter)
Sudhakar Agnihothram, BPharm, PhD

**Designated Federal Officer (DFO)**
Cicely Reese, PharmD

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

These summary minutes for the June 18, 2026, meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) were approved on the 20 of September 2026.

I certify that I participated in the June 18, 2026, meeting of the VRBPAC meeting and that these minutes accurately reflect what transpired.

/s/
Cicely Reese, PharmD, LCDR
USPHS, DFO

/s/
Arnold S. Monto, MD
Acting Chairperson

Food and Drug Administration
Center for Biologics Evaluation and Research
Summary Minutes
193rd Vaccines and Related Biological Products Advisory Committee Meeting

**June 18, 2026**

On June 18, 2026, the 193rd meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) convened in open session to discuss and make recommendations on the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA), manufactured by Moderna TX Inc., with a requested indication in Biologics License Application STN 125869/0 for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine.

On June 18, 2026, at 8:30 a.m. Eastern Daylight Time (EDT), Dr. Arnold Monto, Acting Chairperson, called the meeting to order. The DFO, Dr. Cicely Reese, made administrative remarks, conducted rollcall, 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. David Kaslow, Office of Vaccines Research and Review, provided the Introduction to the VRBPAC Meeting Topics, and Dr. Joseph Kulinski provided a brief review of Biologics License Application for STN 125869/0, followed by Questions and Answers (Q&A).

Following Introductory Remarks and Overview, the Center for Disease Control and Prevention (CDC), a Guest Speaker on Seasonal Influenza Vaccines, regulated industry and FDA presenters provided presentations entitled:

- CDC: Seasonal Influenza Vaccine Surveillance and Effectiveness: Lisa Grohskopf, MD, MPH
- Seasonal Influenza Vaccines: Current Status and Opportunities for Improved Effectiveness: Richard Webby, PhD
- Moderna Presentations:
    - Moderna Investigational Influenza Vaccine mRNA-1010 in Adults = 50 Years: Rituparna Das, MD, PhD
    - Epidemiology of Seasonal Influenza in US Adults =50 Years and Effectiveness of Current Vaccines: Evan Anderson, MD, FIDSA, FPIDS
    - Clinical Data: Efficacy and Immunogenicity of mRNA-1010: Rituparna Das, MD, PhD
    - Clinical Safety: Eleanor Wilson, MD, MHS
    - Benefit-Risk and Summary: Rituparna Das, MD, PhD
- FDA Presentation: FDA Review of Efficacy, Immunogenicity, and Safety of MFLUSIVA (Influenza Vaccine, mRNA) in Adults 50 Years of Age and Older: Gauri Raval, MD, MPH; Timothy P. Brennan, MD, PhD, MS

A 40-minute lunch break was held after the FDA presentation.

After the lunch break, Dr. Monto convened the Open Public Hearing (OPH). Four registered speakers presented remarks during the OPH. The Chairperson closed the session and moved into presentations to the Committee.

Immediately following the OPH, an additional Q&A session was held for the CDC, Industry, and FDA Presenters.

**June 18, 2026**

The Chairperson began the general Committee Discussion of the topic. After the general discussion concluded, the Chairperson and DFO invited and led the Committee into the voting session. The outcome of the voting questions is noted below:

**Voting Question 1:** Do the benefits of mFlusiva outweigh its risks for the prevention of influenza disease in adults 50 through 64 years of age?

The vote was Yes: 9 No: 0 Abstain: 0.

**Voting Question 2:** Do the benefits of mFlusiva outweigh its risks for the prevention of influenza disease in adults 65 years of age and older?

The vote was Yes: 9 No: 0 Abstain: 0.

**Meeting Summary:**

The 193rd VRBPAC meeting, held on 18 June 2026, focused on evaluating the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA; mRNA-1010), manufactured by Moderna, for the prevention of influenza disease in adults 50 years of age and older. Committee members broadly supported the benefit-risk profile of MFLUSIVA. Discussion topics included labeling of the elevated reactogenicity profile, need for the second season data, establishment of correlates of protection, assessment of cell-mediated immunity and strain selection framework for mRNA-based influenza vaccines. Members emphasized the need for data in populations including immunocompromised, frail adults, and pregnant women. The committee voted unanimously 9–0 on both questions, recommending that the benefits of MFLUSIVA outweigh its risks for adults 50 through 64 years of age (supporting traditional approval) and for adults 65 years of age and older (supporting accelerated approval).

Following Committee voting and the summary, Acting Chairperson, Dr. Arnold Monto, invited Dr. Kaslow to provide closing remarks. Dr. Kaslow thanked the committee for the 193rd VRBPAC meeting, which discussed the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA), manufactured by Moderna TX Inc., with a requested indication in Biologics License Application STN 125869/0 for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine.

Following Dr. Kaslow's closing remarks, the committee DFO adjourned the meeting on June 18, 2026, at 2:53 p.m. EDT.

Additional meeting information and details can be obtained from the transcript, which can be viewed at:
2026 Meeting Materials, Vaccines and Related Biological Products Advisory Committee | FDA.

The recording of the webcast of the meeting June be viewed at:
**https://youtube.com/live/9W18lwG7vD8**