

**Food and Drug Administration
Center for Biologics Evaluation and Research**

**SUMMARY MINUTES
169th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

October 14-15, 2021

Committee Members

Hana El Sahly, M.D., Chair +
Archana Chatterjee, M.D., Ph.D.
CAPT. Amanda Cohn, M.D.
Hayley Gans, M.D.
Holly Janes, Ph.D. +
Michael Kurilla, M.D., Ph.D.
Myron Levine, M.D., D.T.P.H., F.A.A.P. +
H. Cody Meissner, M.D.
Paul Offit, M.D.
Steven Pergam, M.D., M.P.H.
Andrea Shane, M.D., M.P.H., M.Sc. +
Paul Spearman, M.D. +
Geeta K. Swamy, M.D. +

Industry Representatives

Paula Annunziato, M.D.
Gregg Sylvester, M.D., M.P.H. <+

Consumer Representative

Randy Hawkins, M.D. * (Acting)

Designated Federal Officer's (DFO)

Prabhakara Atreya, Ph.D.
Kathleen Hayes, M.P.H.

Committee Management Specialist(s)

Monique Hill, M.H.A.

* Consumer Representative

+ Not in attendance

< Alternate Industry representative

Temporary Voting Members

Arnold Monto, M.D. (Acting Chair)
A. Oveta Fuller, Ph.D.
James Hildreth, Sr., Ph.D., M.D.
Jeannette Lee, Ph.D.
Ofer Levy, M.D., Ph.D.
Patrick Moore, M.D., M.P.H.
Michael Nelson, M.D., Ph.D.
Stanley Perlman, M.D., Ph.D.
Eric Rubin, M.D., Ph.D.
Mark Sawyer, M.D., F.A.A.P.
Melinda Wharton, M.D., M.P.H.

Speakers and Guest Speakers

Sharon Alroy-Preis, M.D., MPH, MBA –
Ministry of Health, Israel
Ron Milo, Ph.D. – Weizmann Institute of
Science, Israel
Kirsten Lyke, M.D. – University of Maryland
School of Medicine
Sponsors – Moderna (Day 1), Janssen (Day 2)

FDA Participants

Sudhakar Agnihothram, B. Pharm., Ph.D.
(Speaker)
Artur Belov, Ph.D. (Speaker)
Timothy Brennan, Ph.D., M.D. (Speaker)
Doran Fink, M.D.
Richard Forshee, Ph.D.
Joohee Lee, M.D. (Speaker)
Peter W. Marks, M.D., Ph.D. (Speaker)
Tina Mongeau, M.D., M.P.H. (Speaker)
Ramachandra Naik, Ph.D. (Speaker)
Narayan Nair, M.D. (Speaker)
Celia M. Witten, Ph.D., M.D.
Jerry Weir, Ph.D.
Hui-Lee Wong, Ph.D. (Speaker)
Rachel Zhang, M.D. (Speaker)

These summary minutes for the October 14-15, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on October 28, 2021

I certify that I participated in the October 14-15, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Prabhakara Atreya, Ph.D.
Designated Federal Officer

_____/s/_____
Arnold Monto, M.D.
Acting Chair

On October 14, 2021 at 8:30 a.m. Eastern Standard Time (EST), Topic I of the 169th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss the Emergency Use Authorization (EUA) of the Moderna COVID-19 mRNA Vaccine for the administration of a booster dose, following completion of the primary series, in individuals 18 years of age and older.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The Designated Federal Officer (DFO), made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that one conflict of interest waiver was issued to a consultant and a temporary voting member, Dr. James Hildreth, under 18 U.S. Code 208 in connection with the meeting and the waiver was posted on the FDA website for public disclosure.

Dr. Peter Marks, Director for the Center for Biologics Evaluation and Research (CBER), FDA made welcoming remarks and introduced the topic of the meeting. Dr. Sudhakar Agnihotram with the Division of Vaccines and Related Product Applications (DVRPA), FDA then provided a background presentation titled “Moderna COVID-19 Vaccine Application for Emergency Use Authorization of a booster dose.” This was followed by a presentation by Dr. Sharon Alroy-Preis with the Ministry of Health, Israel and Dr. Ron Milo with the Weizmann Institute, Israel, made a presentation titled, “Booster protection across ages – data from Israel.” Following their presentations, the Committee was released for a 15-minute break. Following the break, Dr. Jacqueline Miller with the sponsor, Moderna Therapeutics, presented, “Safety and Immunogenicity of a 50 µg Booster Dose of mRNA-1273 (Moderna COVID-19 Vaccine).

After the sponsors presentations concluded, Dr. Tina Mongeau with OVRP, CBER, FDA provided a follow-up presentation titled “FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine (mRNA-1273) Booster Dose Emergency Use Authorization” and Dr. Hui-Lee Wong with the Office of Biostatistics and Epidemiology, CBER, FDA presented, “Surveillance Updates of Myocarditis/Pericarditis and mRNA COVID-19 Vaccination in the FDA BEST System.” Following the FDA presentations, the Committee was then released to a 30-minute lunch break. Once the Committee returned from lunch, a 60-minute Open Public Hearing (OPH) session was held in which 7 public pre-registered speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website.

Following the OPH session, the Committee was released for a 15-minute break and once the Committee returned from the break, proceeded with the supplemental question and answer (Q&A) session for the Sponsor and FDA presenters. After the Q&A session, the voting and discussion portion of the meeting was held in which the VRBPAC was asked to vote on the following question:

Do available data support the safety and effectiveness of Moderna COVID-19 Vaccine for use under EUA as a booster dose (50 mcg mRNA-1273) at least 6 months after completion of a primary series in the following populations:

- **Individuals 65 years of age and older,**
- **Individuals 18 through 64 years of age at high risk of severe COVID-19, and**
- **Individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.**

Please vote Yes or No.

The results of the vote were as follows: Yes = 19, No = 0, Abstain =0.

There were no concerns raised by the committee regarding this unanimous vote.

Following the vote, the committee was presented with the following discussion question:

Considering the information presented today and at the meeting of the VRBPAC on September 17, 2021, including updated information on effectiveness of mRNA COVID-19 vaccines, please discuss whether available data support use of a mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) booster dose administered at least 6 months after completion of the same mRNA COVID-19 vaccine primary series in the general population of adults in an age group less than 65 years.

- **For the purposes of this question, age groups below 18 years should not be considered**

The committee discussed the potential for lowering the age for use of mRNA COVID vaccine boosters in the general population on this first day of the meeting and did not feel that the data presented were highly compelling for lowering the age for their administration to all adults 18 years of age and older or to all adults within a narrower age range below 65 years [see also minutes for October 15, 2021].

Following the discussion, the meeting for Topic I was then adjourned on October 14, 2021 at 4:30 PM EST.

On October 15, 2021 at 8:30 a.m. Eastern Standard Time (EST), Topic II of the 169th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss the EUA of the Janssen Biotech Inc. COVID-19 vaccine for the administration of a booster dose, to individuals 18 years of age and older.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO made administrative

remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that one conflict of interest waiver was issued to a consultant and a temporary voting member, Dr. James Hildreth, under 18 U.S. Code 208 in connection with the meeting and the waiver was posted on the FDA website for public disclosure.

Dr. Peter Marks, Director for the Center for Biologics Evaluation and Research (CBER), FDA made welcoming remarks and introduced the topic of the meeting. Dr. Sudhakar Agnihotram with the Division of Vaccines and Related Product Applications (DVRPA), FDA then provided a background presentation titled “Janssen COVID-19 Vaccine Application for Emergency Use Authorization of a booster dose.” Dr. Penny Heaton with the sponsor, Janssen, and supplemental presenters, gave a presentation titled, “Emergency Use Authorization (EUA) Amendment for a Booster Dose for the Janssen COVID-19 Vaccine (Ad26.COV2.S)

After the sponsors presentations concluded, Dr. Rachel Zhang and Dr. Timothy Brennan both with OVRP, CBER, FDA provided a follow-up presentation titled, “FDA Review of Effectiveness and Safety of Janssen COVID-19 Vaccine (Ad26.COV2.S) Booster Dose Emergency Use Authorization Amendment.” Dr. Artur Belov with OBE, CBER, FDA then presented “Review of RWE to Assess the Effectiveness of a single dose of Janssen COVID-19 Vaccine (Ad26.COV2.S)” and Dr. Narayan Nair also with OBE, CBER, FDA, presented “Review of Post Authorization Safety Data for Janssen COVID-19 Vaccine.”

Following the FDA presentations, the Committee was then released to a 10-minute break. Once the Committee returned from break, a 60-minute Open Public Hearing (OPH) session was held in which only 2 public pre-registered speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website. Following the OPH session, the Committee was released for a 15-minute break and once returned, proceeded with a supplemental Q&A session for the Sponsor and FDA presenters. Following the Q&A, the Committee was released for a 30-minute lunch break. Once the Committee returned from the break, the Committee went into the voting and discussion portion of the meeting.

The VRBPAC was asked to vote on the following question:

Do available data support the safety and effectiveness of Janssen COVID-19 Vaccine for use under EUA as a booster dose in individuals 18 years and older at least 2 months after a single dose primary vaccination?

- a. If yes to # 1, do available data support that an interval of at least 6 months between a single primary dose and a booster dose may result in a more robust booster response?**
- b. If no to # 1, do available data support the safety and effectiveness of Janssen COVID-19 Vaccine for use under EUA as a booster dose in individuals 18 years and older at least 6 months after a single dose primary vaccination?**

Please vote Yes or No.

The results of the vote were as follows: Yes = 19, No = 0

The advisors noted the overall lower effectiveness of the single dose of the Janssen vaccine compared with the mRNA COVID vaccines and indicated that apparent disparity helped provide justification for a second dose. The advisors requested that the voting question be simplified, and thus follow-up question 1a was not put forth. In their discussion, the advisors did not consider the available data compelling to support that a 6-month interval would result in a more robust booster response compared with a 2-month interval. Several advisors raised the concern that more of the data presented by the sponsor had not been independently verified by FDA prior to the meeting.

Following the vote, the committee heard a presentation by Dr. Kirsten Lyke with the University of Maryland School of Medicine titled “DMID 21-0012 – Heterologous Platform Boost Study Mix and Match.” Following Dr. Lyke’s presentation, the VRBPAC was presented with the following discussion question:

Taking into consideration the limitations of the study design and sample size, please discuss any general observations that can be made regarding the data on heterologous boosters presented by NIH from their Mix and Match Booster Study.

The advisors as a group found the study presented by NIH to be well conducted and informative on the safety and effectiveness of heterologous booster doses. Acknowledging the limitations of the data, the committee endorsed implementing the use of heterologous boosters at this time to facilitate the administration of booster doses to eligible individuals.

At the very end of the day, the committee returned to the discussion of potentially lowering the age for use of mRNA COVID vaccine booster doses in the general population. The renewed discussion focused on the fact that the COVID-19 pandemic is dynamic and that additional data on the need for booster inoculations are emerging. Following the discussion, a number of advisors indicated support for lowering the eligible age to 40 or 50 years. Many were uncomfortable with lowering the age further, until there are more data on myocarditis.

Following the discussion, the meeting for Topic II was then adjourned on October 15, 2021 at 3:28 PM 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 the following links:

- **10/14 - Day 1**
 - Youtube: <https://youtu.be/BhlshZ7Lkr0>**External Link Disclaimer**
- **10/15 - Day 2**
 - Youtube: <https://youtu.be/c-H40GrvWz4>**External Link Disclaimer**