

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

**SUMMARY MINUTES  
167th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY  
COMMITTEE**

**September 17, 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**

Jay Portnoy, 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.  
Pamela McInnes, D.D.S., M.Sc.  
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**

Donna Boyce, MS – Pfizer Inc.  
Jonathan Sterne, Ph.D. – Univ. of Bristol, UK  
Sara Oliver, M.D., MSPH – CDC  
Sharon Alroy-Preis, M.D., MPH, MBA –  
Ministry of Health, Israel  
Ron Milo, Ph.D. – Weizmann Institute of  
Science, Israel  
William Gruber, M.D. – Pfizer Inc.

**FDA Participants**

Doran Fink, M.D.  
Joohee Lee, M.D. (Speaker)  
Marion Gruber, Ph.D. (Speaker)  
Philip Krause, M.D.  
Peter W. Marks, M.D., Ph.D.  
Ramachandra Naik, Ph.D. (Speaker)  
Celia M. Witten, Ph.D., M.D.  
Jerry Weir, Ph.D.

These summary minutes for the September 17, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on September 22, 2021.

I certify that I participated in the September 17, 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 September 17, 2021 at 8:30 a.m. Eastern Standard Time (EST), the 167th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss Pfizer-BioNTech’s supplemental Biologics License Application for administration of a third dose, or “booster” dose, of the COVID-19 vaccine, COMIRNATY, in individuals 16 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 Dr. Marion Gruber, Director of the Office of Vaccines Research and Review (OVR), FDA introduced the topic of the meeting with a presentation titled “Application for Licensure of a Booster Dose of COMIRNATY, COVID-19 Vaccine, mRNA.” Dr. Ramachandra Naik of OVR, CBER, FDA then provided a background presentation titled “Comirnaty (COVID-19 Vaccine, mRNA) Supplemental Biologics License Application for a booster dose in individuals 16 years of age and older.” This was followed by a presentation by Dr. Sarah Oliver with the Centers for Disease Control and Prevention (CDC) titled “Updates to COVID-19 Epidemiology and COVID-19 Vaccines.” Dr. Jonathan Sterne with the University of Bristol Medical School then gave a presentation on “Real-world effectiveness of COVID-19 vaccines.” 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 against confirmed infections and severe disease – data from Israel.” Following their presentations, the Committee was released for a 5-minute break. After the break, speakers Ms. Donna Boyce and Dr. William Gruber with the sponsor, Pfizer Inc. presented, “BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] Booster (Third) Dose.”

After the sponsors presentations concluded, Dr. Joohee Lee with OVR, CBER, FDA provided a follow-up presentation titled “FDA Review of Effectiveness and Safety of COMIRNATY (COVID-19 Vaccine, mRNA) Booster Dose Biologics License Application Supplement.” The Committee was then released to a 25-minute lunch break. Once the Committee returned from

lunch, a 60-minute Open Public Hearing (OPH) session was held in which 17 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 proceeded with the discussion portion of the meeting.

The VRBPAC was then asked to vote on the following question:

- 1. Do the safety and effectiveness data from clinical trial C4591001 support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age and older?**

**Please vote Yes or No.**

**The results of the vote were as follows: Yes = 2, No = 16.**

Thus, the committee voted against approval of a booster dose for individuals 16 years of age and older. Committee members expressed concern regarding uncertainties about the benefit afforded by a booster dose relative to the benefit provided by previous vaccination with the primary series in persons 16 years of age and older. Concerns were expressed about post-authorization data demonstrating increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose of COMIRNATY with the highest risk in males 16 to 17 years of age. There is currently only limited data whether this risk may be further increased after a booster dose of COMIRNATY. Some committee members also noted the absence of robust data regarding the effectiveness of a booster dose against the currently circulating Delta variant of SARS-COV-2.

Considering the committee's feedback, the FDA then asked the committee members to vote on whether the available data would support an emergency use authorization of a booster dose for individuals 65 years and older. Prior to VRBPAC members casting their vote, FDA provided them with a brief overview of applicable EUA criteria.

The committee was presented with a second voting question:

- 2. Based on the totality of scientific evidence available, including the safety and effectiveness data from clinical trial C4591001, do the known and potential benefits outweigh the known and potential risks of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 65 years of age and older?**

**Please vote Yes or No.**

**The results of the vote were as follows: Yes = 18, No = 0.**

Thus, the committee voted unanimously that the known and potential benefits outweigh the known and potential risks of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for individuals 65 years of age and older. Following the vote, the committee expressed support

that the EUA include individuals at high risk of occupational exposure to COVID-19.

Following the discussion, the meeting was then adjourned on September 17, 2021 at 4:45 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: [Vaccines and Related Biological Products Advisory Committee – 9/17/2021 - YouTube](#).