Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
167th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

October 26, 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.
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
Fiona Havers, M.D. - CDC
Matthew Oster, M.D., M.P.H. – CDC
William Gruber, M.D. – Pfizer Inc.

FDA Participants
Leslie Ball, M.D. (Speaker)
Doran Fink, M.D. (Speaker)
Peter W. Marks, M.D., Ph.D.
Ramachandra Naik, Ph.D. (Speaker)
Celia M. Witten, Ph.D., M.D.
Jerry Weir, Ph.D.
Hui-Lee Wong, Ph.D. (Speaker)
Hong Yang, Ph.D. (Speaker)

These summary minutes for the October 26, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on November 10, 2021.

I certify that I participated in the October 26, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Prabhakara Atreya, Ph.D.
Designated Federal Officer

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Arnold Monto, M.D.
Acting Chair

On October 26, 2021 at 8:30 a.m. Eastern Standard Time (EST), the 170th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss Pfizer-BioNTech's Emergency Use Authorization request for administration of their COVID-19 mRNA vaccine to children 5 to 11 years of age.

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. Doran Fink, Deputy Director – Clinical, of the Division of Vaccines and Related Product Applications (DVRPA), Office of Vaccines Research and Review (OVRR), FDA introduced the topic of the meeting with a presentation titled "Pfizer-BioNTech COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, Use of a 2-Dose Primary Series in Children 5-11 Years of Age." Dr. Ramachandra Naik of OVRR, CBER, FDA then provided a background presentation titled "Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Amendment Request for Use in Children 5 through 11 Years of Age." This was followed by a presentation by Dr. Fiona Havers with the Centers for Disease Control and Prevention (CDC) titled "Epidemiology of COVID-19 in Children Aged 5-11 Years." Dr. Matthew Oster, also with the CDC presented "mRNA COVID-29 Vaccine-Associated Myocarditis." Following their presentations, the Committee was released for a 15-minute break. After the break, Dr. William Gruber with the sponsor, Pfizer Inc. presented, "BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine) – Request for Emergency Use Authorization for Individuals 5 to < 12 Years of Age."

After the sponsors presentations concluded, Dr. Leslie Ball with OVRR, CBER, FDA provided a follow-up presentation titled "FDA Review of Effectiveness and Safety of Pfizer-BioNTech COVID-19 Vaccine in Children 5 through 11 Years of Age Emergency Use Authorization

Amendment," Dr. Hui-Lee Wong with the office of Biostatistics and Epidemiology (OBE), FDA presented "Post-Market Active Surveillance of COVID-19 Vaccines in the Pediatric Population in the FDA BEST System," and Dr. Hong Yang, OBE, FDA presented " Benefits-Risks of Pfizer-BioNTech COVID-19 Vaccine for Ages 5 to 11 Years." The Committee was then released to a 35-minute lunch break. Once the Committee returned from lunch, a 60-minute Open Public Hearing (OPH) session was held in which 18 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. **Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age?**

   Please vote Yes, No, or Abstain.

   The results of the vote were as follows: Yes = 17, No = 0, Abstain = 1.

Discussion Summary:

The VRBPAC discussion focused mainly on the anticipated benefits of vaccination in this age group weighed against the uncertain risk of myocarditis. Commenting on FDA's quantitative benefit-risk modeling, advisors noted that FDA likely overestimated the risk of myocarditis in relying on non-chart confirmed case numbers from the adolescent age group but also may have overestimated numbers of COVID hospitalizations prevented by not accounting for the proportion of children in this age group who are now seropositive and may therefore have natural immunity. Some advisors questioned whether authorization could be more focused to use in higher-risk subgroups, while other advisors noted that one-third of hospitalized COVID cases in this age group were in children without known risk factors. Some advisors also expressed that data are needed to inform the optimal dosing regimen in this age group, and for children with prior SARS-CoV-2 infection. Ultimately, most advisors agreed that while the burden of COVID is less in this age group compared with older age groups, and while COVID incidence in the US is currently declining, available data supported that the demonstrated benefits of the vaccine outweigh the risks in the general population of children 5-11 years of age, even accounting for relevant uncertainties.

Following the discussion, the meeting was then adjourned on October 26, 2021 at 4:35 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: https://youtu.be/laaLo_xKmmA