Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
164th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

June 10, 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)
Lori Dodd, Ph.D.
A. Oveta Fuller, Ph.D.
James Hildreth, Sr., Ph.D., M.D.
David Kim, M.D., M.A.
Ofer Levy, M.D., Ph.D.
Pamela McInnes, D.D.S., M.Sc.
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
Arthur Phyllis, M.B.A. – Industry
(Biotechnology Innovation Organization)
Hannah Kirking, M.D. - CDC
Tom Shimabukuro, M.D., M.P.H., M.B.A - CDC
Shannon Stokley, DrPH, M.P.H. - CDC

FDA Participants
Steven Anderson, Ph.D. (Speaker)
Doran Fink, M.D. (Speaker)
Marion Gruber, M.D.
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 June 10, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 8, 2021.

I certify that I participated in the June 10, 2021 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____	_____/s/_____
Prabhakara Atreya, Ph.D.	Arnold Monto, M.D
Designated Federal Officer	Acting Chair

On June 10, 2021 at 8:30 a.m. Eastern Standard Time (EST), the 166th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss, in general, data needed to support authorization and/or licensure of COVID-19 vaccines for use in pediatric populations.

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. Ramachandra Naik of FDA provided an introductory presentation titled "Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19 for Use in Pediatric Populations." This was followed by a presentation by LCDR Hannah Kirking with the Centers for Disease Control and Prevention (CDC) titled "Epidemiology of SARS-COV-2 in Children and Adolescents." Dr. Shannon Stokley with the CDC then made a presentation on "Adolescent COVID-19 Vaccination." This presentation was followed by Dr. Steven Anderson discussing "FDA Updates of COVID-19 Vaccines Safety Activities" and Dr. Tom Shimabukuro with the CDC presenting "COVID-19 Vaccine Safety Update." Following their presentations, the Committee was released for a 10-minute break. After the break, Dr. Doran Fink with the FDA presented "Considerations on Data to Support Licensure and Emergency Use Authorization (EUA) of COVID-19 Vaccines for Use in Pediatric Populations."

After Dr. Finks presentations concluded and a supplemental 30-minute Q&A session was held, Ms. Arthur Phyllis from BIO (Expand) made a\ presentation titled "Industry Perspective: Considerations for COVID-19 Vaccine Pediatric Trials." . 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 8 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.

There were three discussion items presented to the Committee:

1. Provided there is sufficient evidence of effectiveness to support benefit of a COVID-19 preventive vaccine for pediatric age groups (e.g., 6 to <12 years, 2 to <6 years, and 6 months to <2 years), please discuss the safety data, including database size and duration of follow-up, that would support:
    a. Emergency Use Authorization
    b. Licensure

Committee members generally acknowledged that COVID vaccines for use in the pediatric populations are needed; however, some members expressed concern that prior to vaccinating millions of healthy children, a better understanding of vaccine-induced adverse events, in particular potential long-term sequelae of myocarditis is needed. Other members opined that issuance of an EUA would depend on the trajectory of the COVID pandemic and emergence of VOCs. Committee members opined that it is critical to conduct vaccine dose response evaluations in pediatric populations and emphasized the need for adequate safety follow-up. The committee members thought that the safety data base, i.e., number of subjects included in pediatric studies with COVID-19 vaccines should be increased (e.g., should be larger than 1,000 subjects per pediatric age cohort) in particular, for the youngest age cohorts. Generally, VRBPAC members agreed that the follow-up time to evaluate subjects for safety should be the same to support a BLA and EUA (e.g., 6 months). There was no consensus whether an EUA should be issued to make COVID-19 vaccines available in the pediatric population.

2. Provided there is sufficient evidence of effectiveness to support benefit of a COVID-19 preventive vaccine for adolescents 12 to <18 years of age, please discuss the safety data, including database size and duration of follow-up, that would support licensure.

The VRBPAC members expressed support for the FDA approach in terms of duration of subject follow-up and safety data base required to support licensure of COVID-19 vaccines in adolescents.

3. Please discuss studies following licensure and/or issuance of an EUA to further evaluate safety and effectiveness of COVID-19 vaccines in different pediatric age groups.

VRBPAC members recommended for the following post-authorization/post-licensure studies to be performed to further evaluate the safety and effectiveness of COVID-19 vaccines in pediatric age groups: studies in racial and ethnic minorities, studies in immune-compromised subjects, immunogenicity studies to evaluate waning of immunity and to determine a correlate of protection, vaccine dose response evaluations specifically tailored to the various pediatric age groups, studies to evaluate different vaccine dose intervals and prime/boost regimen, safety studies to better understand the potential of vaccine-induced enhanced disease and myocarditis.

Following the discussion, the meeting was then adjourned on June 10, 2021 at 3:30 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://www.youtube.com/watch?v=7oXhn3K9SlQ