Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
152nd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

May 17, 2018

Committee Members
Kathryn Edwards, M.D.,Chair+
Hana El Sahly, M.D.
Ofer Levy, M.D., Ph.D. +
Holly Janes, Ph.D.
Pamela McInnes, D.D.S., M.Sc. *
Arnold Monto, M.D.
Paul Offit, M.D. +
Andrea Shane, M.D., M.P.H., M.Sc.
Melinda Wharton, M.D., M.P.H. +

FDA Speakers
Darcie Everett, M.D., M.P.H.
Cara Fiore, Ph.D.

Guest Speakers
Judith Absalon, M.D., M.P.H.
Annaliesa Anderson, Ph.D., F.A.A.M.
Carol Baker, M.D.
Shabir Madhi, M.B.B.Ch., FCPaeds ^
Stephanie Schrag, D.Phil. #

Designated Federal Officer (DFO)
Serina A. Hunter-Thomas, M.S.A., R.N.

Committee Management Specialist
Rosanna Harvey

+ Not in attendance
# Temporary Non-Voting Member and Speaker
* Acting VRBPAC Chair
^ Via Teleconference

Temporary Voting Members
Karin Bok, Ph.D.
Peter Gilbert, Ph.D.
Robert Phillips Heine, M.D.
Karen Kotloff, M.D.
Myron Levine, M.D., D.T.P.H., F.A.A.P.
Paul Spearman, M.D.

Consumer Representative
Sheldon V. Toubman, J.D. ^

Industry Representative
David Greenberg, M.D.

Temporary Non-Voting Member
Stephanie Schrag, D.Phil. #

FDA Participants
Carolyn Wilson, Ph.D.
Marion Gruber, Ph.D.
Philip Krause, M.D.
Konstantin Chumakov, Ph.D.
Jerry Weir, Ph.D.

These summary minutes for the May 17, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on June 11, 2018.

I certify that I participated in the May 17, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Serina A. Hunter-Thomas,
Designated Federal Officer

/s/
Pamela McInnes, D.D.S., M.Sc. (Dent.)
Acting Chair

On May 17, 2018 at 8:05 a.m. Eastern Standard Time (EST), Dr. Pamela McInnes, Acting VRBPAC Chair, called to order the 152nd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Topic I "Approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant." The Acting Chair invited everyone around the table to introduce themselves, followed by the DFO's administrative remarks and reading of the Conflict of Interest (COI) statement into the public record. There were no waivers issued for conflicts of interest for this meeting. The meeting proceeded with Dr. Cara Fiore who gave the FDA introductory presentation titled "Evaluation of the Effectiveness of Vaccines Intended to Prevent Group B Streptococcal Disease in Infants – Introduction and Background," followed by Dr. Darcie Everett who gave a presentation titled "GBS Young Infant Disease Burden, Trends and Prevention Strategies: High Income Countries," followed by a presentation from Dr. Carol Baker titled "GBS Conjugate Vaccine: Early Development and Correlates of Protection." The next presentation was from Dr. Shabir Madhi, who joined us via teleconference from South Africa. Dr. Madhi's presentation was titled "Clinical and Immunological Epidemiology of GBS in Low-Middle Income Settings." Dr. Madhi's presentation was followed by Pfizer's Dr. Annaliesa Anderson and Dr. Judith Absalon who presented on "The Burden of GBS Disease and Pfizer's GBS Vaccine" and "Potential GBS Vaccine Clinical Development Pathways" respectively. After Pfizer's presentations, the Committee broke for lunch, and then reconvened for the Open Public Hearing portion of the meeting. There were two speakers for the OPH session, Dr. Keith Klugman, and Dr. Kirsty Mehring-Le Doare. Following the Open Public Hearing for Topic I, the committee proceeded to the Committee Discussion portion of the meeting. There were three discussion points presented to the committee:

1. In addition to laboratory confirmed early or late onset disease, what additional clinical disease endpoints (i.e., unconfirmed and confirmed fetal or infant endpoints, maternal endpoints) could be considered to demonstrate vaccine effectiveness? Please discuss their strengths and limitations.
2. Could immunological endpoints (i.e., functional and ligand binding antibody levels) be used to demonstrate vaccine effectiveness? If so, please discuss their strengths and limitations.
3. Could colonization be used to demonstrate vaccine effectiveness? If so, please discuss its strengths and limitations.

For Discussion Question Number 1, the committee was encouraged to not focus on the regulatory path for the FDA, but rather the bigger picture, which was identifying strengths and limitations of studies with a focus on clinical disease endpoints (both early and late onset) versus immunological endpoints versus colonization. The committee mentioned group B strep related stillbirths, maternal disease, pre-term birth, neonatal encephalopathy and sepsis as aspects to consider for the first question.

Regarding Discussion Question Number 2, the Committee's comments included efforts to standardize assays, serological correlates, the need for additional data (both animal and epidemiological), post-licensure studies and inclusion/exclusion criteria for immunological endpoints.

On Discussion Question Number 3, the Committee brought up clarifying points regarding maternal colonization versus neonatal and infant colonization, as well as rectal versus vaginal colonization.

Following the Committee Discussion, there was a 15-minute break, after which at approximately 2:55 p.m. Eastern Standard Time (EST), the meeting proceeded to Topic II, Presentation of the Laboratory of Respiratory Viral Diseases (LRVD) Division of Viral Products (DVP) of the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). After the COI statement was read by the DFO, the presentations began starting with Dr. Carolyn Wilson, who provided an overview of the Research/Site Visit Process in CBER. This was followed by an overview of the Division of Viral Products by Dr. Jerry Weir, and then an overview of the Laboratory of Respiratory of Viral Diseases by Dr. Zhiping Ye. Dr. Ye's presentation was followed by the Topic II Open Public Hearing (OPH) session. There were no speakers present to comment during this OPH part of the meeting.

On May 17, 2018 at 3:45 p.m. Eastern Standard Time (EST), the Committee met in closed session which lasted until 4:20 p.m. Eastern Standard Time (EST).

The meeting was adjourned at 4:20 p.m. on May 17, 2018.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

Part 1: https://collaboration.fda.gov/p1q1ckshspc/
Part 2: https://collaboration.fda.gov/p4coiorls09/