

Food and Drug Administration  
Center for Biologics Evaluation and Research

SUMMARY MINUTES  
146<sup>th</sup> VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY  
COMMITTEE

May 17, 2017

**Committee Members**

Kathryn Edwards, M.D., Chair  
Hana El Sahly, M.D.+  
Janet Englund, M.D. +  
David Greenberg, M.D.\*  
Holly Janes, Ph.D.  
Karen Kotloff, M.D.  
Ofer Levy, M.D., Ph.D. +  
Sarah Long, M.D.  
Ruth Lynfield, M.D.  
Pamela McInnes, D.D.S., M.Sc.  
Arnold Monto, M.D.  
Patrick Moore, M.D.,  
M.P.H.+  
Mark Sawyer, M.D.  
Melinda Wharton, M.D., M.P.H.

**Temporary Voting Members**

Luigi Notarangelo, M.D.  
Ralph Tripp, M.D.

**Temporary Voting Consumer  
Representative\*\***

Jay Portnoy, M.D.

**Speakers**

**FDA**

Jeff Roberts, M.D., FDA  
Sarah Browne, M.D., FDA

**Speaker**

Susan Gerber, M.D., CDC

**Guest Speaker**

Fernando Polack, M.D., Fundacion Infant

**Industry Speakers**

Ilse Dieussaert, GSK  
Roland Zahn, Ph.D., Janssen  
Melanie Saville, M.D., Janssen

**FDA Participants,**

Philip Krause, M.D.  
Jerry Weir, Ph.D.  
Wellington Sun, M.D.

**Designated Federal Officer**

Serina Hunter-Thomas, M.S.A., R.N.

**Committee Management Specialist**

Denise Royster

+ Not in attendance

\* Industry Representative

\*\* Temporary Consumer Representative

These summary minutes for the May 17, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 20, 2017.

I certify that I participated on the May 17, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/S/  
Serina Hunter-Thomas  
Designated Federal Officer

/S/  
Kathryn Edwards, M.D.  
Chair

On May 17, 2017 at 8:30 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 146th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the topic “Considerations for Evaluation of Respiratory Syncytial Virus (RSV) Vaccine Candidates in Seronegative Infants.” The meeting was held in an open session. The Chair invited the members, temporary members, and the participants seated at the table to introduce themselves. The Designated Federal Officer (DFO) made administrative remarks and read the Conflict of Interest statement into the public record. There were no waivers issued for conflicts of interest for this meeting. After the Conflict of Interest statement was read for the public record by the DFO, the FDA and non-FDA speaker presentations began.

An introduction and overview of the topic along with the three discussion topics were presented by Dr. Jeff Roberts from the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). Dr. Susan Gerber from the Centers for Disease Control (CDC) provided an overview of RSV Epidemiology. This was followed by a presentation entitled, “Understanding Enhanced RSV Disease” by Dr. Fernando Polack from Fundación INFANT, Buenos Aires, Argentina. After a brief break, Dr. Sarah Browne from OVRR, CBER made a presentation entitled, “Development of Vaccine for Prevention of Respiratory Syncytial Virus (RSV) Disease in RSV-naïve Infants.” This was followed by a presentation on the Pediatric RSV Vaccine Program by Ilse Dieussaert of GlaxoSmithKline.

After the lunch break, the committee reconvened for the Open Public Hearing (OPH) session. Oral comments were made by Dr. Megan Polanin from the National Center for Health Research and Dr. Ruth Karron, Director of the Center for Immunization Research at the Bloomberg School of Public Health, Johns Hopkins University.

Following the OPH, a joint presentation entitled, “Development of a Vaccine for Prevention of Respiratory Syncytial Virus disease in RSV-naïve Infants” was made by Dr. Roland Zahn and Dr. Melanie Saville of Janssen Vaccines & Prevention

After completion of the presentations, committee discussion began on the following points:

1. Please discuss the preclinical data essential to support studies of RSV vaccines in RSV-naïve infants, with regard to the potential risk of vaccine-associated ERD.
  - Please consider the impact of vaccine type, antigen, and/or other relevant factors.
2. Please discuss the role of clinical data from adults and RSV-experienced infants to support evaluation of RSV vaccines in RSV-naïve infants.
3. Please discuss how studies in RSV-naïve infants could be designed to mitigate concerns about ERD throughout clinical development.
  - Please consider aspects of initial study design such as eligibility criteria, age de-escalation, and duration of follow-up.
  - Please consider relevant aspects of Phase 3 study design.

VRBPAC discussed the preclinical data needed to support studies in RSV-naïve infants and agreed that more than a single animal should be studied and many recommended that candidate vaccines be tested in three animal models prior to testing in RSV-naïve infants . There was consensus among members regarding the need to have standardized assays, viruses, and animal models for comparison. Immunogenicity (i.e. cellular and humoral responses) and safety data from adults and RSV-experienced infants should support evaluation of RSV vaccines in RSV-naïve infants, although everyone agreed that studies in adults and RSV-experienced infants would not predict any subsequent risk of ERD for a RSV-naïve infant population. Studies in RSV-naïve infants should include thoughtful education and informed consent so parents understand the risks and benefits of vaccination. To ensure the safety of the infants in the study, close and continuous monitoring is required. Eligibility criteria should include particularly healthy babies with no underlying medical conditions with consideration for length of gestational age.

The meeting was adjourned at 3:42 p.m. on May 17, 2017.

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/p3yut1uwwi3/>

Part 2: <https://collaboration.fda.gov/p713gh98r06/>