

Food and Drug Administration  
Center for Biologics Evaluation and Research

SUMMARY MINUTES  
141<sup>st</sup> VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY  
COMMITTEE MEETING

January 14, 2016

**Committee Members**

Robert Daum, M.D., C.M., Chair  
Kathryn Edwards, M.D.  
Janet Englund, M.D.  
Michael Hudgens, Ph.D.  
Karen Kotloff, M.D.  
Sarah Long, M.D.  
Ruth Lynfield, M.D.  
Patrick Moore, M.D., M.P.H.  
Pedro Piedra, M.D.  
Mark Sawyer, M.D.  
Ofer Levy, M.D., Ph.D. +  
Theodore Tsai, M.D.#+

**FDA Participants**

Carolyn Wilson, Ph.D.  
Marion Gruber, Ph.D.  
Konstantin Chumakov, Ph.D.  
Jerry Weir, Ph.D.  
Steven Rubin, Ph.D.

**Temporary Voting Member**

Vicky Pebsworth, Ph.D., R.N. \*

**Temporary Non-Voting Member**

Filip Dubovsky, M.D. \*\*

**Designated Federal Officer**

Sujata Vihj, Ph.D.

**Committee Management Specialist**

Denise Royster

+ Not in attendance

# Industry Representative

\* Temporary Consumer Representative  
(Consumer Representative Position is Vacant)

\*\* Alternate Industry Representative

These summary minutes for the January 14, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on February 16, 2016.

I certify that I participated on the January 14, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

-/Signed/-

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Sujata Vijn, Ph.D.  
Designated Federal Officer

-/Signed/-

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Robert Daum, M.D., C.M.  
Chair

On January 14, 2016 at 1:00 p.m. Eastern Standard Time (EST), Dr. Robert Daum, the Chair of VRBPAC, called to order the 141<sup>st</sup> Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). This partially closed meeting addressed the June 17, 2015 site visit of the intramural research programs of the Laboratory of Method Development (LMD), in the Division of Viral Products, Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER).

The meeting was held at the Food and Drug Administration (FDA), 10993 New Hampshire Avenue, Building 31, Silver Spring, MD 20993. VRBPAC members participated via teleconference for the open and closed sessions and watched the publicly available live webcast during the open session. The public was also welcome to attend the open session of the meeting at the FDA headquarters.

After the meeting was called to order by the Dr. Daum, the Designated Federal Officer (DFO) took a roll call of the VRBPAC members for the public record and made administrative remarks following which the FDA staff introduced themselves. The conflict of interest statement was read by the DFO for the public record noting that this was a non-particular matter meeting.

### **Open Session**

During the open session, the committee heard presentations of an overview of the CBER Research and Site Visit Process from CBER's Associate Director for Research, Dr. Carolyn Wilson. An overview of OVR's research programs was provided by Dr. Konstantin Chumakov followed by an overview of the Division of Viral Products from its Director, Dr. Jerry Weir. Following these presentations, Dr. Steven Rubin, the Chief of the Laboratory of Method Development, gave an overview of his research program and the progress that was made since the previous site visit. The committee was given the opportunity to ask clarifying questions following which an Open Public Hearing session was announced. However, since no public members were present and there was no

public comment, the open session was adjourned at 1:55 p.m. and the meeting proceeded to the closed session.

Details of the open session may be obtained from the official transcript of the meeting that is available at

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm474746.htm>