

Food and Drug Administration  
Center for Biologics Evaluation and Research

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

November 7, 2017

**Committee Members**

Kathryn Edwards, M.D., Chair  
Hana El Sahly, M.D.  
Janet Englund, 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 Non-Voting Members**

Eugene Blackstone, M.D.  
Karin Bok, M.S., Ph.D.  
Dean Follmann, Ph.D.  
John S. Kirkpatrick, M.D.  
David Stephens, M.D.

**Consumer Representative\*\***

Sheldon Toubman, J.D.

**Industry Representative\***

David Greenberg, M.D.

**FDA Speakers**

Tina Mongeau, M.D., M.P.H.  
Jeff Roberts, M.D.

**FDA Participants**

Marion Gruber, Ph.D.  
Philip Krause, M.D.  
Wellington Sun, M.D.

**Speaker**

Michael Otto, Ph.D., M.S.

**Guest Speaker**

Richard Proctor, M.D.

**Pfizer Speakers**

Thomas Errico, M.D.  
Bill Gruber, M.D., F.A.A.P., F.I.D.S.A.  
Javad Parvizi, M.D., F.R.C.S.

**Administrative Team**

**Designated Federal Officer**

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

**Committee Management Specialists**

Rosanna Harvey

Joyce Mercer-Dickens

**Director**

Prabhakara Atreya, Ph.D.

Division of Scientific Advisors and Consultants

+ Not in attendance

\* Industry Representative

\*\* Consumer Representative

^ Participating by Phone

These summary minutes for the November 7, 2017 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on December 15, 2017.

I certify that I participated in the November 7, 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 November 7, 2017 at 8:30 a.m. Eastern Standard Time (EST), the Chair, Dr. Kathryn Edwards, called to order the 150th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss and make recommendations on the clinical development plan for Pfizer's investigational *Staphylococcus Aureus* vaccine intended for pre-surgical prophylaxis in elective orthopedic surgical populations. The meeting was held in an open session in its entirety. 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 two discussion topics were presented by Dr. Jeffrey Roberts from the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). The FDA overview was followed by presentation from Dr. Michael Otto from the National Institutes of Health on "Scientific Considerations: Pathogenesis of *Staphylococcus Aureus* Infection." Following Dr. Otto's presentation, Dr. Richard Proctor provided a presentation on "*Staphylococcus Aureus* Vaccines: Clinical Trials and Basic Science Challenges." Following Dr. Proctor's presentation, the sponsor presentations by Pfizer representatives began. Dr. Thomas Errico provided a presentation titled "Spinal Surgery and Infection" followed by Dr. Javad Parvizi's presentation titled "Orthopedic Infections: Challenging Problem." The last sponsor presentation by Dr. Bill Gruber was titled "Proposed Plan and Rationale to Support a SA4Ag Indication in Elective Orthopedic Surgery." The sponsor presentations were followed by the Open Public Hearing (OPH) session during which there were no attendees. The meeting therefore continued with a presentation from Dr. Tina Mongeau, who presented on "Considerations for Pfizer's Investigational *Staphylococcus aureus* Vaccine Intended for Pre-Surgical Prophylaxis in Elective Orthopedic Surgical Populations." Following Dr. Mongeau's presentation, the

committee proceeded with the discussion portion of the meeting. Committee discussion began with a review of the following topics previously presented during the first presentation:

1. Assuming that the ongoing study of SA4Ag achieves its pre-specified primary efficacy objective in a population undergoing elective, posterior-approach, instrumented, multilevel spinal fusion surgery, please discuss the reasons why efficacy should or should not be generalized to other elective orthopedic surgical populations.
2. Assuming that the ongoing study of SA4Ag demonstrates safety in a population undergoing elective, posterior-approach, instrumented, multilevel spinal fusion surgery, please discuss the reasons why safety should or should not be generalized to other elective orthopedic surgical populations

For the committee discussion portion of the meeting, the committee agreed that although there is a great need for a staph aureus vaccine, there remains some concern regarding the efficacy data presented, and the generalizability to other surgical populations. The committee encouraged the sponsor to broaden the inclusion criteria for a Phase 3 study, and recommendations were given for ways to have greater power.

The meeting was adjourned at 3:31 p.m. on November 7, 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/p3b3ub7rbc4/>

Part 2: <https://collaboration.fda.gov/p8n89o9tk84/>

Part 3: <https://collaboration.fda.gov/p1q1bxksx72/>