Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
150th 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.
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.

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

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

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/          /S/
Serina Hunter-Thomas      Kathryn Edwards, M.D.
Designated Federal Officer     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/