

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
150<sup>th</sup> Meeting of the Vaccines and Related Biological Products Advisory  
Committee  
FDA White Oak Campus, Building 31, Great Room  
Silver Spring, MD**

**November 7, 2017**

**AGENDA  
Meeting Link:**

<https://collaboration.fda.gov/cbervrpac2017>

Topic: The committee will meet in an open session to discuss and make recommendations on the clinical development plan for Pfizer's investigational *Staphylococcus aureus* vaccine intended for pre-surgical prophylaxis in elective surgical populations.

<b>Time</b>	<b>Presentation/Presenter</b>
<b>8:30 am</b>	<p><b><u>Opening Remarks: Call to Order, Introduction of Committee</u></b>  <b>Kathryn Edwards, M.D.</b>            Chair, VRBPAC</p> <p><b><u>Administrative Announcements, Conflict of Interest Statement</u></b>  <b>Serina Hunter-Thomas, M.S.A., R.N.</b>            Designated Federal Officer, VRBPAC            CBER, FDA</p>
<b>8:45 am</b>	<p><b><u>FDA Presentation: Clinical Development of Pfizer's Investigational <i>Staphylococcus aureus</i> Vaccine for Prevention of Postoperative Infection in Elective Orthopedic Surgeries</u></b></p> <p>Jeff Roberts, M.D.            Chief, Clinical Review Branch 1            Division of Vaccines and Related Product Applications (DVRPA)            Office of Vaccines Research and Review (OVRR)            Center for Biologics Evaluation and Research (CBER)            Food and Drug Administration (FDA)</p>
<b>9:00 am</b>	<p><b><u>Scientific Considerations: Pathogenesis of <i>Staphylococcus aureus</i> Infection</u></b></p> <p>Michael Otto, Ph.D., M.S.            Chief, Pathogen Molecular Genetics Section            National Institute of Allergy and Infectious Diseases (NIAID)            National Institutes of Health (NIH)</p>

<b>Time</b>	<b>Presentation/Presenter</b>
<b>9:45 am</b>	<p><b><u>Clinical Considerations: Postoperative <i>Staphylococcal</i> Infection, Disease Manifestations, and Therapeutic Options</u></b></p> <p>Richard Proctor, M.D.  Professor Emeritus of Medical Microbiology and Immunology  University of Wisconsin School of Medicine and Public Health  Madison, Wisconsin</p>
<b>10:30 am</b>	Break
<b>10:45 am</b>	<p><b><u>Sponsor Presentations:</u></b></p> <p><b><u>Orthopedic Infections: Challenging Problem</u></b>  Javad Parvizi M.D., F.R.C.S.  James Edwards Professor of Orthopaedic Surgery  Sidney Kimmel School of Medicine  Rothman Institute at Thomas Jefferson University</p> <p><b><u><i>S. aureus</i> Surgical site Infection (SSI) in Spinal Surgery</u></b>  Thomas Errico, M.D.  Professor of Orthopedic Surgery and Neurosurgery  NYU School of Medicine</p> <p><b><u>Proposed Plan and Rationale to Support a SA4Ag Indication in Elective Orthopedic Surgery</u></b>  Bill Gruber, M.D., F.A.A.P., F.I.D.S.A.  Senior Vice President  Vaccine Clinical Research &amp; Development  Pfizer Inc.</p>
<b>12:10 pm</b>	Lunch
<b>1:10 pm</b>	Open Public Hearing
<b>2:10 pm</b>	<p><b><u>FDA Presentation: Considerations for Pfizer's Investigational <i>Staphylococcus aureus</i> Vaccine Intended for Pre-Surgical Prophylaxis in Elective Orthopedic Surgical Populations</u></b></p> <p>Tina Mongeau, M.D., M.P.H.  Medical Officer  DVRPA, CBER, FDA</p>
<b>2:40 pm</b>	Committee Discussion
<b>4:40 pm</b>	Adjourn Meeting