

# Meningococcal Vaccines Work Group Update

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Advisory Committee on Immunization Practices

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# Work Group Members

## **ACIP Members**

Lorry Rubin (Chair)

Doug Campos-Outcalt

## ***Ex Officio* Members**

Lucia Lee (FDA)

Meghan Ferris(FDA)

## **Designated Federal Officer**

Jessica MacNeil (CDC/NCIRD)

## **Liaison and Other Representatives**

Mike Brady (AAP)

Susan Even (ACHA)

Rachel Herlihy (IAC)

Nneka Holder (SAHM)

Martin Luta (CSTE)

Jeffrey Moore (AAFP)

William Schaffner (NFID)

Bill Atkinson

Carol Baker

Richard Clover

Scott Kapoor

Paul McKinney

Cody Meissner

Paul Offit

Georges Peter

David Stephens

# Serogroup B Meningococcal (MenB) Vaccines

- ❑ At present, a MenB vaccine has not been licensed in the United States
- ❑ Two investigational MenB vaccines are under development
  - Both vaccines have received a “Breakthrough Therapy” designation from FDA
  - Pfizer Vaccines has submitted a complete BLA to FDA
  - Novartis Vaccines has submitted a rolling BLA to FDA
    - Licensed in Europe, Australia, and Canada

## Use of MenB Vaccine for Outbreak Response

- ❑ In 2013, 2 universities experienced outbreaks of serogroup B meningococcal disease with a combined 13 cases and one death reported
- ❑ Vaccination campaigns were conducted at both universities in response to the outbreaks using an investigational MenB vaccine (Novartis Vaccines) obtained through an expanded access Investigational New Drug (IND) application sponsored by CDC

# Meningococcal Outbreak Work Group

- ❑ Ad hoc work group comprised of ACIP Meningococcal Work Group members, ACIP members, state public health officials, college health professionals, and CDC
  - Convened January 30, 2014 with biweekly meetings
- ❑ Objectives:
  - Review available data on the recent epidemiology of meningococcal disease and outbreaks
  - Develop guidance for use of MenB vaccines under a CDC-sponsored IND in an outbreak setting
  - Update the current meningococcal outbreak guidelines once MenB vaccines are licensed in the United States

## Today's Session

- ❑ Epidemiology of meningococcal disease outbreaks in the United States (Sarah Meyer, CDC)
- ❑ Interim guidance for the use of a serogroup B meningococcal vaccine under a CDC-sponsored expanded access IND (Jessica MacNeil, CDC)
- ❑ No votes will be taken

# ACIP Meningococcal Work Group: Additional Activities

- ❑ **Policy Note: Use of Menveo in infants at increased risk for meningococcal disease**
  - Published on June 20, 2014
  - Summarizes the use of 3 meningococcal conjugate vaccines in children age 2 through 23 months at increased risk
  
- ❑ **Approach to recommendations for use of serogroup B vaccines once licensed**