

# Maternal Immunization Working Group Phase II



**11 February 2015  
NVAC**

**Chairs:  
Richard Beigi, MD  
Saad Omer, PhD**

# Maternal Immunizations Facts

- Pregnant women and young infants are at a higher risk for morbidity and mortality from various vaccine-preventable diseases
- A provider recommendation and vaccine offering during pregnancy are key factors that help increase vaccination coverage
- Maternal immunization can help foster positive attitudes towards vaccines in pregnant women that may result in greater awareness, acceptance, and demand for vaccines for both themselves and their children

# Maternal Immunization Updates: Pregnancy and Lactation Labeling Final Rule

Prescription Drug Labeling Sections 8.1 - 8.3 USE IN SPECIFIC POPULATIONS

## CURRENT LABELING

8.1 Pregnancy

8.2 Labor and Delivery

8.3 Nursing Mothers

## NEW LABELING

(effective June 30, 2015)

8.1 Pregnancy  
includes Labor and Delivery

8.2 Lactation  
includes nursing mothers

**NEW**  
8.3 Females and Males  
of Reproductive  
Potential

The PLLR removes pregnancy letter categories – A, B, C, D and X. The PLLR also requires the label to be updated when information becomes outdated <sup>1</sup>

<sup>1</sup> Roberts and Gruber, Regulatory considerations in the clinical development of vaccines indicated for use during pregnancy . Vaccine. January 2015

# NVAC CHARGE FOR THE MIWG

## CHARGE

**The Assistant Secretary for Health charges the NVAC to:**

**Part 1:**

- Review the current state of maternal immunization and existing best practices
- Identify programmatic barriers to the implementation of current recommendations related to maternal immunization and make recommendations to overcome these barriers <sup>1</sup>

**Part 2:**

- **Identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers**

<sup>1</sup> Reducing Patient and Provider Barriers to Maternal Immunizations, Public Health Reports, Jan-Feb 2015

# MEMBERSHIP

## NVAC

**Rich Beigi (Co-chair), Saad Omer(Co-chair)  
Walt Orenstein, Ruth Lynfield, Sarah Depres, Seth Hetherington**

## NVPO leads

**Jennifer Gordon  
Karin Bok**

## Subject Matter Experts

**Ajoke Sobanjo-ter Meulen, Steven Black, Mary Healy, Cindy Pellegrini, Flor Muñoz, Jan Bonhoeffer, D. Tomianovic, Geeta Swamy, Kathy Edwards, Leonard Friedland, Debra Hawks, Jeanne Sheffield, N.Bhat, Debbie Higgins, Fernando Polack, Cheryl Broussard, Gina Burns, Sharon Humiston, Amina White, Carol Baker**

## Ex Officio Federal Liaisons

**Karen Broder (CDC)  
Jennifer Liang (CDC)  
Stacey Martin (CDC)  
Pedro Moro (CDC)  
Marion Gruber (FDA)  
Jeff Roberts (FDA)  
Valerie Marshall (FDA)  
Avril Houston (HRSA)  
Emily Levine (HHS/OGC)  
Barbara Mulach (NIH)  
Mirjana Negin (NIH)  
Jennifer Read (NIH)  
Margaret Jacovone (DoD)  
Fran Cunningham (VA)  
Richard Martinello (VA)**

## Special Assistant

**Katy Seib**

**THANK YOU**

