Combination Vaccines Working Group
Advisory Committee on Immunization Practices (ACIP)

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Background

- **Combination vaccines**
  - Combine equivalent component vaccines into single products to prevent more than one disease or to protect against multiple strains of infectious agents causing the same disease
  - Reduce the number of injections
  - Reduce concern regarding number of injections
  - Improve coverage and timeliness

General Recommendations on Immunization, 2011; Combination Vaccines for childhood Immunization,1999

Terms of Reference

1. **Review published and unpublished data related to the safety and immunogenicity of the**

    1. Quadracel DTaP IPV vaccine for children 4 through 6 years

    2. Investigational hexavalent pediatric vaccine (DTaP5-IPV-Hib-HepB) 3 dose series for children at 2, 4, and 6 months

Quadracel

- Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and inactivated Poliovirus Vaccine (Sanofi Pasteur)
- Second DTaP-IPV vaccine licensed for use in children 4 through 6 years of age
- Indicated for use as fifth dose in DTaP series and fourth or fifth dose in IPV series, in children who have received 4 doses of Pentacel or Daptacel
- Biologics License Application (BLA) submitted to FDA 3/24/2014
- BLA accepted by FDA for review 5/22/2014
- FDA approved licensure 3/24/2015

Quadracel – Immunogencity and Safety

- **Pre-licensure Pivotal Clinical Trial: M5102**
- **Multicenter, randomized, controlled, Phase 3 clinical trial comparing DTaP-IPV (Quadracel) to separately administered DTaP (Daptacel) and IPV (IPOL®) vaccines in children 4-6 years who were primed with 4 doses of Daptacel or Pentacel**
  - Quadracel induced non-inferior antibody responses compared to separately administered Daptacel and IPOL vaccines for all evaluated immunogenicity parameters
  - Rates of solicited injection-site and systemic reactions, unsolicited AEs, and SAEs were comparable among the vaccination groups

Investigational Pediatric Hexavalent Vaccine

- **Sanofi Pasteur and Merck**
  - Diphtheria, Tetanus, Pertussis (DTaP5), Polio (IPV), *Haemophilus influenzae* type b (Hib; PRP-OMPC), Hepatitis B (HepB)
  - 3 dose series (2, 4, 6 months)
- **Biologics License Application (BLA) accepted by FDA for review in October 2014**
- **Licensure anticipated Fall of 2015**
- **July - September: Merck and Sanofi present to WG; review of safety and immunogenicity data**
- **October: present hexavalent pediatric vaccine to ACIP, VFC vote**
- **November/December: draft MMWR Notice to Readers**

Work Group Members

ACIP Members

Art Reingold, Chair

Marietta Vázquez

***Ex Officio* Member**

Ann Schwartz, FDA

Liaison Representatives

Elizabeth Miller, AAPA

Elizabeth Rosenblum, AAFP

Kathy Edwards, AAP

Patsy Stinchfield, NAPNAP

CDC Co-leads

Gina Mootrey

Jennifer Liang

Work Group Members - SMEs

- Elizabeth Briere – Hib
- Andrew Kroger – General recommendations, Immunization program
- Jennifer Liang – Pertussis
- Pedro Moro – Immunization safety
- Sarah Schillie - Hepatitis
- Tej Tiwari – Diphtheria, Tetanus
- Greg Wallace – Polio