**AAP Webinar Series** 

**Vaccine Hesitancy:** 

Advocating for Children April 3, 2015:

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#### What Is Vaccine Hesitancy?

- Intent to skip or delay at least 1 of the vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)
- Uncertainty as to whether a vaccine should be administered in accordance with the ACIP recommended immunization schedule

**References: 1.** Heller G, Roberts M. Turning the tide: addressing vaccine hesitancy and timely immunizations through a social marketing campaign. Presented at: 44th National Immunization Conference, Atlanta, Georgia, April 21, 2010. Abstract 22697. **2.** Opel DJ, et al. *Hum Vaccines.* 2011;7(4):419-425. **3.** Dempsey AF, et al. *Pediatrics.* 2011;128(5):848-856. **4.** Gust DA, et al. *Pediatrics.* 2008;122(4):718-725.

#### Vaccine Hesitancy: Not a New Problem

- Turn of the 19th century: Vaccination is introduced in the US
- 1809: Massachusetts is the first state to make smallpox vaccination compulsory
- 1850s: US anti-vaccination movement arises in response to the proliferation of smallpox vaccination mandates
  - Activists object to regulations requiring submission to a procedure that involves discomfort and that might not be safe
- 1870s: Smallpox re-emerges in the US, as a result of a decline in vaccination rates
  - Opposition to vaccination increases as new laws are passed and old ones to control smallpox are reinforced

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### **Evolution of Public Health Laws Concerning Vaccination**

- 1905: Jacobson v Massachusetts establishes rights of states to pass and enforce vaccination laws
  - Not a federal jurisdiction
- 1910: First philosophical exemption law is passed
- 1922: Supreme Court finds school immunization laws constitutional
- 1970s: Immunization laws are strengthened and strongly enforced
- 2015: School immunization laws vary among states
  - 50 states permit medical exemptions
  - 48 states permit religious exemptions
  - 19 states permit personal belief exemptions

**References: 1.** Omer SB, et al. *N Engl J Med.* 2009;360(19):1981-1988. **2.** Dr. John Talarico, California Department of Public Health, personal communication, October 5, 2011. **3.** National Conference of State Legislatures. States with religious and philosophical exemptions from school immunization requirements. http://bit.ly/14m1gjt. Accessed April 28, 2014.

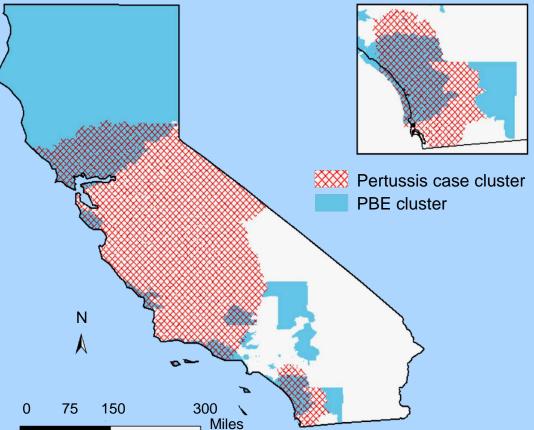
#### Impact of Non-Medical Exemptions on Vaccination Rates

- Overall mean state-level rates of non-medical exemptions have increased; pace of that increase has accelerated
- Vaccination coverage rates are lower in states with personal belief exemptions than in states permitting only religious exemptions
- Children with non-medical exemptions tend to aggregate within schools and communities
- Vaccine-preventable diseases tend to cluster in areas where exemption rates are highest

References: 1. Omer SB, et al. N Engl J Med. 2012;367(12):1170-1171. 2. Omer SB, et al. N Engl J Med. 2009;360(19):1981-1988. 3. Omer SB, et al. JAMA. 2006;296(14):1757-1763. 4. Buttenheim A, et al. Am J Public Health. 2012;102(8):e59-e67. 5. Centers for Disease Control and Prevention (CDC). MMWR. 2014;63(22):496-499.
6. Omer SB, et al. Am J Epidemiol. 2008;168(12):1389-1396. 7. Imdad A, et al. Pediatrics. 2013;132(1):37-43.
8. Atwell JE, et al. Pediatrics. 2013;132(4):624-630.

# Role of PBEs in the Resurgence of Pertussis: California, 2010<sup>1</sup>

- In 2010, the incidence of pertussis was higher in PBE clusters than in areas outside those clusters
- From 2005–2010, the mean census-tract–level rate of PBEs had increased among the state's incoming kindergartners



As illustrated in the larger map, clusters of pertussis cases in California with onset in 2010 overlapped with PBE clusters. The inset shows the relative locations of case clusters and PBE clusters in San Diego County.

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Reference: 1. Atwell JE, et al. *Pediatrics*. 2013;132(4):624-630.

#### High Incidence of Measles in States That Allow PBEs: US, 2011

Red check marks indicate states that allow PBEs and had a high incidence of measles during 2011

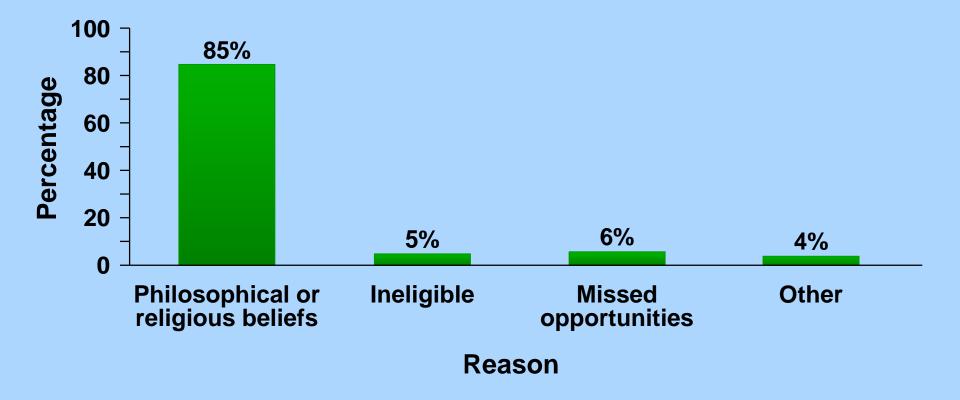


<sup>a</sup> Import-associated describes cases brought into the US from other countries; cases linked epidemiologically to importations of measles into the US; cases with virologic evidence suggesting recent importation; and cases linked to patients with virologic evidence of recent importation. Map reproduced from CDC.<sup>1</sup>

**References: 1.** CDC. *MMWR.* 2012;61(15):253-257. **2.** National Conference of State Legislatures. States with religious and philosophical exemptions from school immunization requirements. http://bit.ly/14m1gjt. Accessed April 28, 2014.

#### High Prevalence of PBEs Among US Residents With Measles: January 1–May 23, 2014<sup>1</sup>

Of the 195 US residents with measles who were unvaccinated against the disease, 85% had philosophical or religious objections.



<sup>a</sup> Figure reproduced from CDC.<sup>1</sup>

Reference: 1. CDC. MMWR. 2014;63(22):496-499.

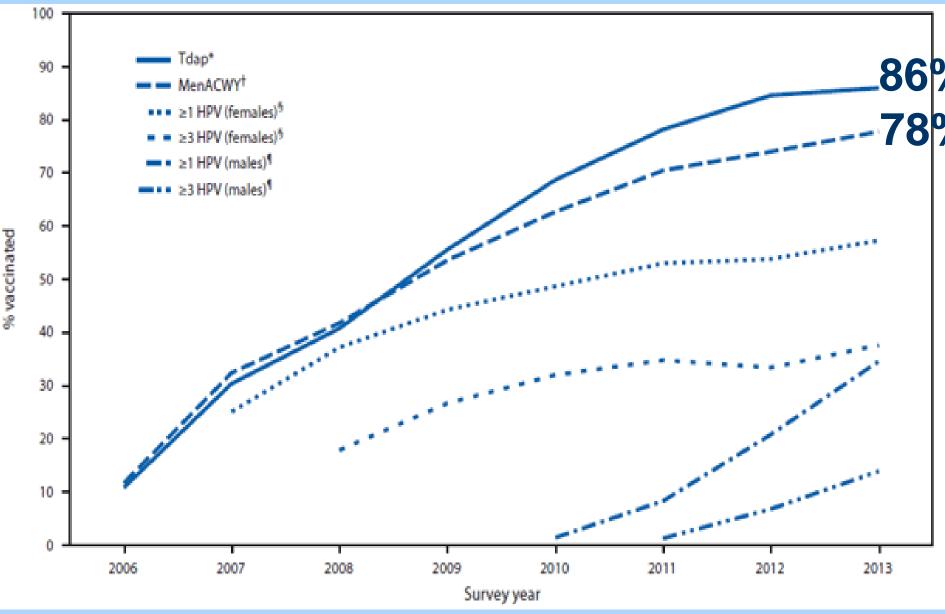
# It's a small world after all

- Disneyland is the epicenter of the 2015 outbreak
- Nearly 200 cases over 17 states
- Almost all cases where details are known have been in unimmunized or under-immunized
- This outbreak has reinvigorated discussions in several states about the public health impact of PBEs
  - Will anything change?

### What about Adolescents

- Vaccine hesitancy is not restricted to parents of young children
- Substantial hesitancy remains among parents of teens, particularly around influenza and HPV vaccines
- What does the national coverage look like for vaccines routinely recommended by ACIP for our teens?

#### **NIS-Teen Vaccine Rates 2006-2013**



## **State by State**

 Healthy People 2020 goal is for 80% or more of 13-15 yr olds to have received Tdap, MCV4, and 3 doses of HPV (females only for now)

- 42 states exceed 80% for Tdap
- 18 states exceed 80% for MCV4
- 0 states exceed 80% for HPV
  - Rhode Island leads at 57%, most states around 40%

# State laws requiring vaccines for middle school

- Tdap: 46 states and DC
- MCV4: 21 states and DC
- HPV: only DC
- Influenza: none
  - Although preschool requirement now for 2 states and NYC

	MCV4 mandated	2013 NIS coverage	Tdap mandated	2013 NIS coverage	
Mississippi	No	50	Yes	60	
Missouri	No	61	Yes	82	
Montana	No	52	Yes	84	
Nebraska	No	78	Yes	86	
Nevada	No	64	Yes	88	
New Hampshire	No	86	Yes	95	
New Jersey	Yes	92	Yes	86	
New Mexico	No	71	Yes	86	
New York	No	83	Yes	90	
North Carolina	Yes	87	Yes	89	
North Dakota	Yes	94	Yes	95	
Ohio	No	69	Yes	84	
Oklahoma	No	66	Yes	78	
Oregon	No	65	Yes	87	
Pennsylvania	Yes	90	Yes	90	

### Strategies to improve vaccine rates

- State mandates make a clear difference
- New mandates are now met with suspicion and reluctance
- Making a vaccine 'required' for school entry (or for work, as in HCP) may have negative consequences as well

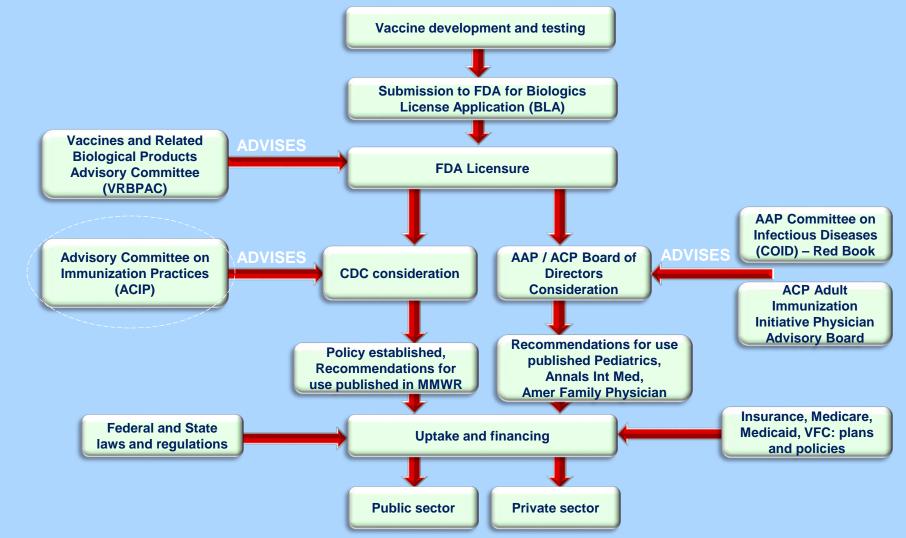
• What is the federal government's role here?

What is the Role of the

Federal Government?

#### Developing Vaccine Recommendations and Policy

#### **Development of Vaccine Recommendations & Policies**



#### **US Immunization Policy Timeline: Key Milestones**

- 1955: Poliomyelitis Vaccination Assistance Act start of Federal funding for immunization
- 1962: Creation of the immunization grant program (Section 317)
- 1963: Creation of National Immunization Program at CDC
- 1964: Establishment of Advisory Committee on Immunization Practices (ACIP)
- 1972: Federal Advisory Committee Act (FACA) ACIP designated as a Federal Advisory Committee
- 1986: Creation National Injury Compensation Program
- 1993: Childhood Immunization Initiative Vaccines for Children (VFC) Program adopted

#### **Immunization Recommending Bodies**

Establishes National IZ Policy, Develops National recommendations



 Advisory Committee on Immunization Practices THE KEY DECISON BODY

 American Academy of Pediatrics Committee on Infectious Diseases –Red Book
 American Academy of

Family Physicians

• American College of Physicians

> American College of Obstetricians and Gynecologists

Advocacy for members, Provide recommendation s for members

#### **ACIP – Background**

- ACIP established 1964 by US Public Health Service
- Role: provide advice and guidance to CDC Director and HHS Secretary on most effective means to prevent vaccine-preventable diseases in the civilian population
  - FDA-licensed vaccines (and unlicensed vaccines if warranted)
  - Vaccines related agents (e.g., antisera, immune globulins, antivirals)
- 3 meetings annually February, June, October; each meeting is 2 days

### **ACIP – Background**

- Agenda items
  - Topics solicited from ACIP members, liaisons, CDC staff and others
  - Finalized by ACIP Steering Committee
- Emergency meeting can be called if warranted
- Follow FACA rules and procedures including meetings that are open to the public with time for public comment
- Meeting slides, live webcast archive, minutes posted on ACIP website
- Recommendations become final once approved by CDC Director and published in MMWR



#### The ACIP Process: Considerations in Development of Recommendations

- FDA licensed indications and schedule
- Disease burden, morbidity and mortality overall and in high risk groups
- Data on safety and efficacy/effectiveness in general and in specific groups
- Acceptability/Feasibility in the context of existing recommendations
- Equity in access to vaccine and good use of public funds (cost effectiveness)
- Recommendations of other groups (e.g., AAP, AAFP, ACP, ACOG)

#### **Evidence Based Recommendations (EBR)**

- EBR approach approved by ACIP in October 2010
- System to be used: Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework\*
- Implemented to date:
  - HPV vaccine in males
  - Hepatitis B vaccine in people with diabetes mellitus
  - Pneumococcal vaccines
  - Meningococcal vaccines
  - Influenza vaccines

\* Ahmed F et al. Methods for developing evidence-based recommendations by the ACIP Vaccine 2011;29(49):9171-9176

# FDA vs ACIP

- FDA licenses the vaccine
  - Safe and effective

• ACIP sets policy and recommended use

- ACIP policy not same as FDA approval/indication
  - Tdap over age 65
  - MCV4 two doses for all teens
  - Zoster ages 50-59

# Immunization Policy Product: Two Immunization Schedules

#### **ACIP establishes National immunization policy**

- 1. ACIP, AAP, and AAFP produce a "harmonized" childhood and adolescent immunization schedule with each vaccine in the context of the other vaccines
- 2. ACIP, AAFP, ACP and ACOG produce a harmonized adult immunization schedule with each vaccine in the context of the other vaccines
- Both schedules:
  - updated annually
  - published in January: MMWR, Pediatrics, Annals Internal Medicine, American Family Physician

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13–15 yrs	16–18 yrs
Hepatitis B <sup>†</sup> (HepB)	1 <sup>st</sup> dose	<b>≪</b> 2 <sup>nd</sup>	dose>		<		3 <sup>rd</sup> dose		>					I		
Rotavirus <sup>2</sup> (RV) RV1 (2-dose series) <del>; RV5 (3-dose series)</del>			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis³ (DTaP: <7 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose			<b></b> 4 <sup>th</sup>	dose>			5 <sup>th</sup> dose				
Tetanus, diphtheria, & acellular pertussis⁴ (Tdap: ≥7 yrs)														(Tdap)		
Haemophilus influenzae type b⁵ (Hib)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See footnote 5		3rd or 4 See for	I <sup>th</sup> dose,> otnote 5								
Pneumococcal conjugate <sup>∉</sup> (PCV13)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose		<b>≺</b> 4 <sup>th</sup>	dose>								
Pneumococcal polysaccharide <sup>6</sup> (PPSV23)																
Inactivated poliovirus <sup>7</sup> (IPV: <18 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	<b>&lt;</b>		3 <sup>rd</sup> dose		>			4 <sup>th</sup> dose				
Influenza <sup>®</sup> (IIV; LAIV) 2 doses for some: See footnote 8						Annual	vaccination (	IIV only) 1 or	2 doses		Annual vao IIV) 1	ccination (LA I or 2 doses	IV or	Annual vacci 1 c	ination (LAIV dose only	or IIV)
Measles, mumps, rubella <sup>9</sup> (MMR)					See foo	otnote 9	< 1 <sup>st</sup> (	dose>				2 <sup>nd</sup> dose				
Varicella <sup>10</sup> (VAR)							< 1 <sup>st</sup> (	lose>				2 <sup>nd</sup> dose				
Hepatitis A <sup>11</sup> (HepA)							<b></b> 2	dose series, S	See footnote	11>						
Human papillomavirus <sup>12</sup> (HPV2: females only; HPV4: males and females)														(3-dose series)		
Meningococcal <sup>13</sup> (Hib-MenCY ≥ 6 weeks; MenACWY-D≥9 mos; MenACWY-CRM ≥ 2 mos)			See footnote 13							1 <sup>st</sup> dose Booster						
Range of recommended ages for aggs for ages for																

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines/recs/vaccines/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

# DISCUSSION