Immunizations and the Legal System

Philip LaRussa, MD

June 24, 2020

Course Number PB-VI01P: Development of a Vaccine During a Pandemic
Course Directors: Philip LaRussa, MD and Lawrence Stanberry MD, PhD

COLUMBIA | VAGELOS COLLEGE OF PHYSICIANS AND SURGEONS
PROGRAM IN VACCINE EDUCATION

Immunizations and The Legal System

- Individual rights vs. the greater good

- Role of the legal system in managing this balance:
  - Mandated vs. recommended
  - School entry & job entry requirements
  - Current legal issues: Autism & thimerosal & MMR

- Investigative reporting/ Wakefield saga

U.S. Supreme Court Decision
Jacobson v Massachusetts, 1905

- 1902 outbreak of smallpox in Cambridge, Mass.
- The Cambridge Board of Health required vaccination of all residents not vaccinated since March 1, 1897
- Reverend Henning Jacobson was concerned about vaccine safety and believed that the Massachusetts statute requiring vaccination violated his personal liberties and his constitutional right to due process.
- He refused to be vaccinated, was convicted & fined $5.
- He appealed unsuccessfully to the Massachusetts Supreme Court and then to the US Supreme Court which affirmed the decision of the Massachusetts Court and upheld the right of the state to mandate vaccination against smallpox.

Horlick, Pediatrics, 2008; Colgrove, State of Immunity, 2006

U.S. Supreme Court Decision
Jacobson v Massachusetts, 1905

- States have the authority to exercise their 10th Amendment "police powers" to require immunizations ***and*** Public health considerations related to the threats posed by transmissible disease trump individual autonomy to refuse health care.
  - **10th Amendment**: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."
  - **Crowley v Christensen, 1890**: "the possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country **essential to the safety, health, peace, good order and morals of the community**. **Even liberty itself, the greatest of all rights, is not an unrestricted license to act according to one's own will**."

Horlick, Pediatrics, 2008; Colgrove, State of Immunity, 2006

Mandatory Vaccination of Health Care Workers
Virginia Mason Hospital v Wash. State Nurses Association

- 2004, hospital mandates compulsory influenza vaccination program after a 6 year ineffective voluntary effort:
  - As of Jan. 1, 2005, anyone without proof of vaccination/ willing to take prophylactic meds faces termination
- Nurses Association files a labor grievance
- Arbitration ruling favors nurses, & the hospital appeals:
  - The basis for the ruling was that the requirement was incorporated into the hospital's "fitness for duty" policy and it amounted to one that "directly affected conditions of employment."
    - As such, the program involved an impermissible alteration of ***employment rules*** without collective bargaining ***rather than*** a ***patient safety and infection control*** measure.

Stewart, Public Health Reports 2010

Mandatory Vaccination of Health Care Workers

- Dec. 21, 2007: U.S. Court of Appeals, 9th Circuit upholds the arbitrator's ruling:
  - workers and employers were free to collectively bargain over immunization status, ***as neither state*** public health laws ***nor federal Medicare hospital conditions of participation*** explicitly required HCW immunization as a condition of employment
  - http://caselaw.findlaw.com/us-9th-circuit/1459666.html

Stewart, Public Health Reports 2010

Mandatory Vaccination of Health Care Workers

- August 2009, New York State Health Commissioner proposes regulations that:
  - as a precondition of employment…..would require immunization against seasonal and H1N1 influenza for HCWs and volunteers who have direct contact with patients or who may expose patients……..
  - Regulates exemptions & allows suspension of the rules if vaccine supply is insufficient

Stewart, Public Health Reports 2010

Mandatory Vaccination of Health Care Workers

- Provider groups sue to overturn the regulations
  - Oct. 16, 2009: temporary restraining order
  - Oct. 22, 2009: Commissioner withdraws regulation due to short supply as specified by the proposed regulation
  - Feb. 2010: NYS Supreme Court dismisses provider claims because the regulation had been withdrawn

Stewart, Public Health Reports 2010

Vaccination of Health Care Workers

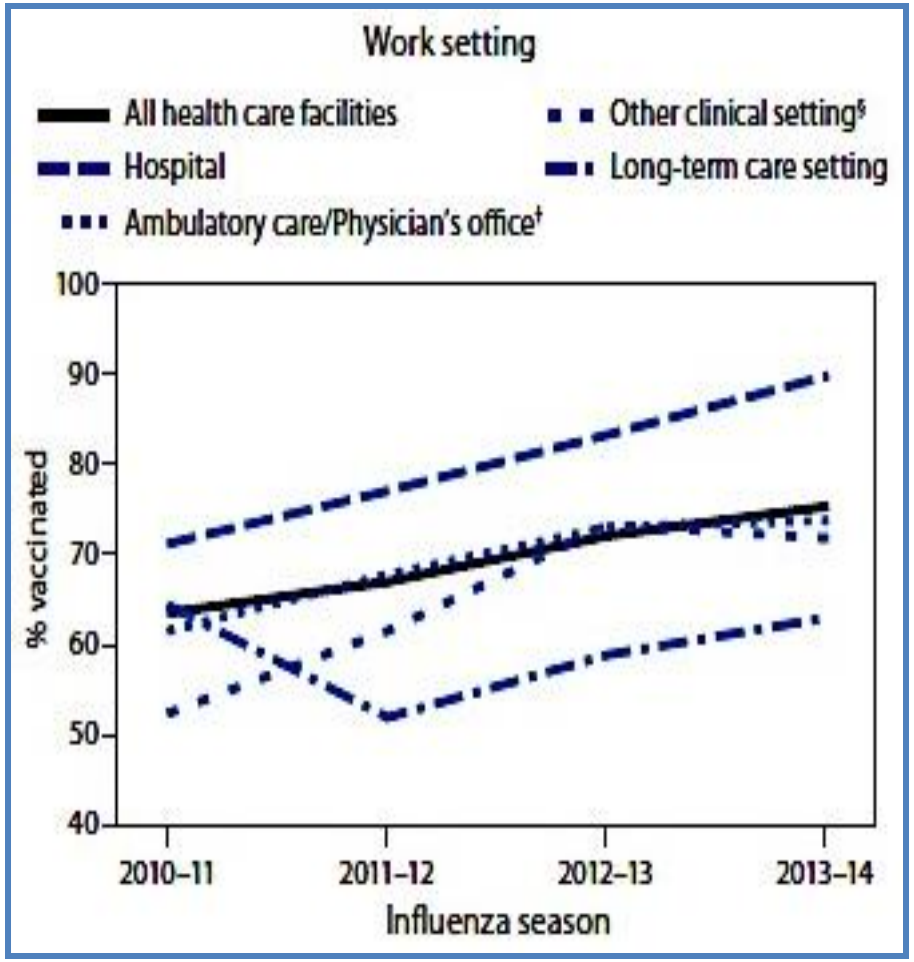
Table 2. Number of states with administration laws, by population and type of vaccine specified

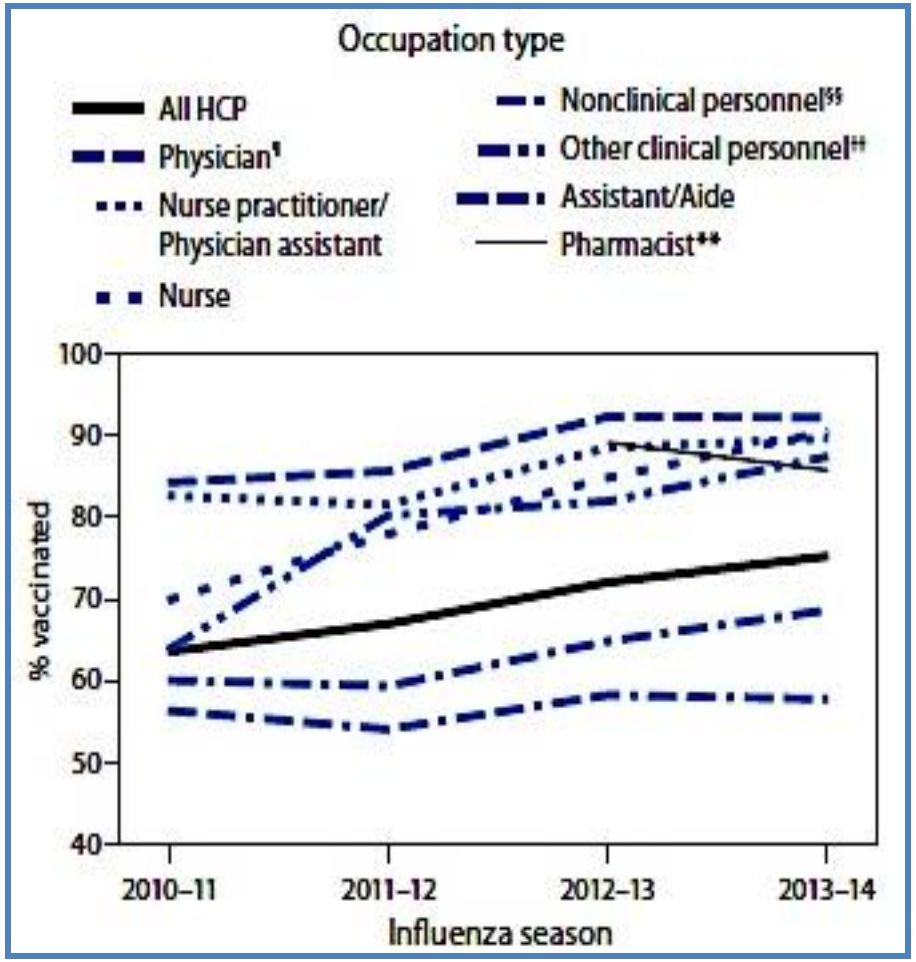
	Healthcare workers[a]		Patients/ residents	
Vaccine type	**Offer**	**Ensure**	**Offer**	**Ensure**
Hepatitis B	20	3	2	8
Influenza	3	3	2	5
Pneumococcal	0	0	2	4
Measles/mumps/rubella	1	11	2	1
Varicella	0	3	0	0
Routine/age-appropriate immunizations[b]	0	1	3	38
Overall number of states with law[c]	21	15	7	40

Ensure laws: ….vaccination of non-immune persons is mandatory in the absence of a specified exemption or a refusal.

Lindley, Am J Prev Med 2007

Influenza Vaccination of Health Care Workers





http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf

State Immunization Laws for Healthcare Workers (2014)

http://www2a.cdc.gov/vaccines/statevaccsApp/default.asp

Vaccine	Ensure	Offer	No
Hepatitis B	2	17	32
Influenza	3	10	38
MMR	10	2	39
Varicella	3	1	47
Pneumococcal	0	0	51

If hospitals are required to ensure that hospital employees are vaccinated against hepatitis b, Influenza, MMR, Varicella, or Pneumococcus, **does the state allow for medical, religious or philosophical exemptions to these requirements**?

- No: 44 States
- Medical only: 4 States
- Medical & Religious: 3 States
- http://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html

Institutional Requirements

New York-Presbyterian Hospital Sites

- All Health care workers joining the workforce on/or after January 1, 2003, are **required to have demonstrable immunity to varicella** as a condition of employment.

  Those individuals who can document a medical contraindication to varicella vaccine are exempt from this requirement.

- **Immunity to Hepatitis B** is **strongly encouraged** for those whose duties may expose them to human blood or body fluids.

  Those who are eligible for but decline Hepatitis B immunization are required by OSHA to sign a declination form.

- **Immunity to measles and rubella is required**. Immunity is documented by serologic tests or adequate vaccination.

  Those who have a documented medical contraindication to the applicable vaccine are exempt from this requirement.

- **Immunity to mumps** is **strongly recommended**, but not required.
- Vaccination is provided free of charge.
- Employees who have evidence of immunocompromise are further evaluated and counseled regarding their risk for acquiring or transmitting infection.

Institutional Requirements

New York-Presbyterian Hospital Sites

- Should New York State mandate influenza vaccination for healthcare workers, NYP will incorporate the mandate into hospital policy.

- In absence of a mandatory state policy, all hospital personnel and affiliated licensed independent practitioners are strongly encouraged to be vaccinated annually against influenza.

NVAC Recommendations, 2012

1. …….health care employers (HCE) and facilities **establish...influenza infection prevention programs** that include education of HCP as a key component…….as an essential step for all HCE and facilities to achieve the Healthy People 2020 influenza vaccine coverage goal.
2. …….HCE and facilities **integrate influenza vaccination programs into existing** infection prevention/ occupational health programs.
3. The ASH encourage CDC and the Centers for Medicare and Medicaid Services (CMS) ……**standardize methodology used to measure** HCP influenza vaccination rates across settings.
4. For those HCE and facilities that have implemented 1, 2, 3 and still have not consistently achieved… 2020 goal for influenza vaccination coverage of HCP….., NVAC recommends that HCE **strongly consider an employer requirement** for influenza immunization.

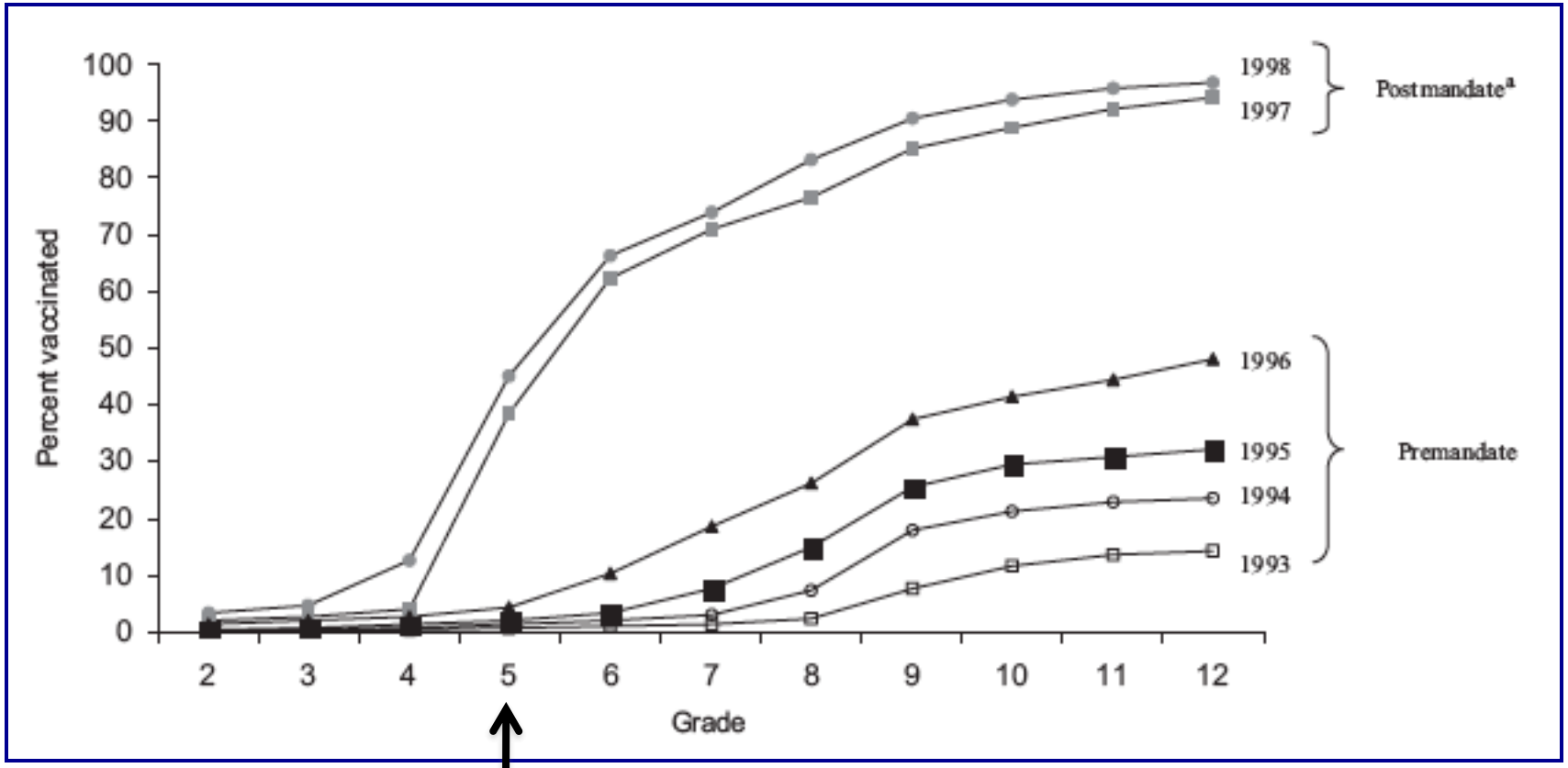
http://www.hhs.gov/nvpo/nvac/reports/index.html

School Entry Requirements

- In 1922, in Zucht v King, the US Supreme Court upheld the constitutionality of Texas city ordinances that required vaccination as a prerequisite for school attendance:
  - Ordinances of the city of San Antonio, Texas, provide that no child or other person shall attend a public school or other place of education without having first presented a certificate of vaccination…..public officials excluded Rosalyn Zucht from a public school because she did not have the required certificate and refused to submit to vaccination. They also caused her to be excluded from a private school.

School Entry Mandates

HBV coverage levels for 6 consecutive cohorts of Chicago public school students before and after State of Illinois Vaccination Mandate



Receipt of HBV required for entry into 5th grade

Morita, Pediatrics 2008

Effect of School Mandates in Reducing Health Care Disparities

TABLE 2 Comparison of Completion of the HBV Series by Chicago Public School Students According to Race/Ethnicity Upon Entry Into 5th and 9th Grades Before and After Mandate

Year[a]	Fifth Grade					Ninth Grade				
	White, %[b]	Black		Hispanic		White, %[b]	Black		Hispanic	
		%[b]	RR (95% CI)	%[b]	RR (95% CI)		%[b]	RR (95% CI)	%[b]	RR (95% CI)
Premandate										
1996	8 (referent)	3	0.35 (0.29–0.43)	4	0.52 (0.43–0.63)	46 (referent)	32	0.70 (0.66–0.74)	40	0.88 (0.83–0.93)
Postmandate										
1997	46 (referent)	33	0.71 (0.68–0.75)	42	0.91 (0.86–0.96)	89 (referent)	84	0.94 (0.92–0.96)	86	0.97 (0.95–0.99)
1998	50 (referent)	39	0.78 (0.74–0.82)	51	1.0 (0.97–1.10)	93 (referent)	89	0.96 (0.95–0.97)	93	1.0 (0.99–1.00)

In 1997, the state of Illinois required receipt of ≥3 doses of hepatitis B vaccine before entry into the 5th grade. RR indicates relative risk.

[a] Year of entry into 5th grade.

[b] Percentage vaccinated (ie, receipt of ≥3 doses of hepatitis B vaccine).

Morita, Pediatrics 2008

Effect of School Entry Requirements

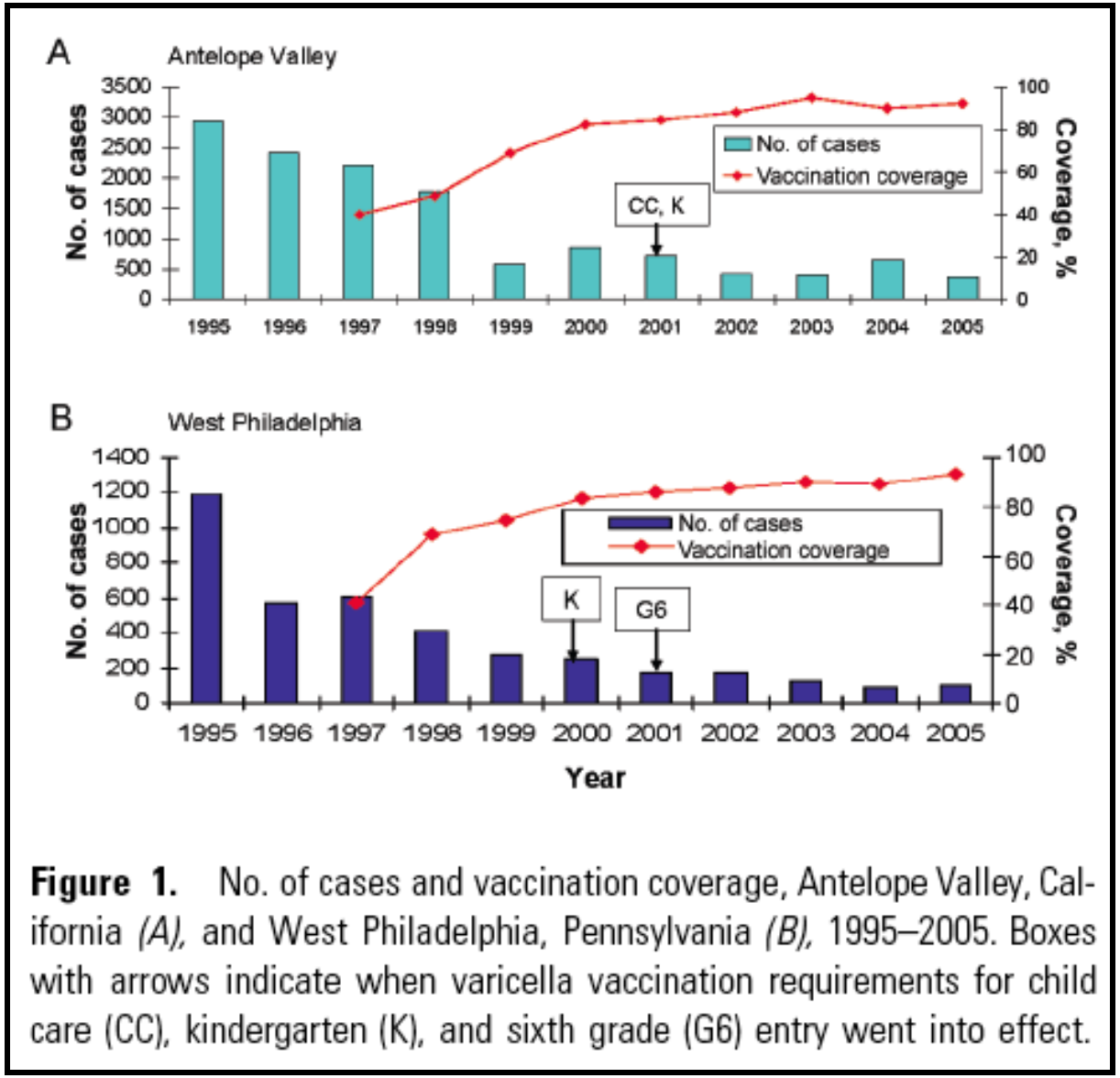
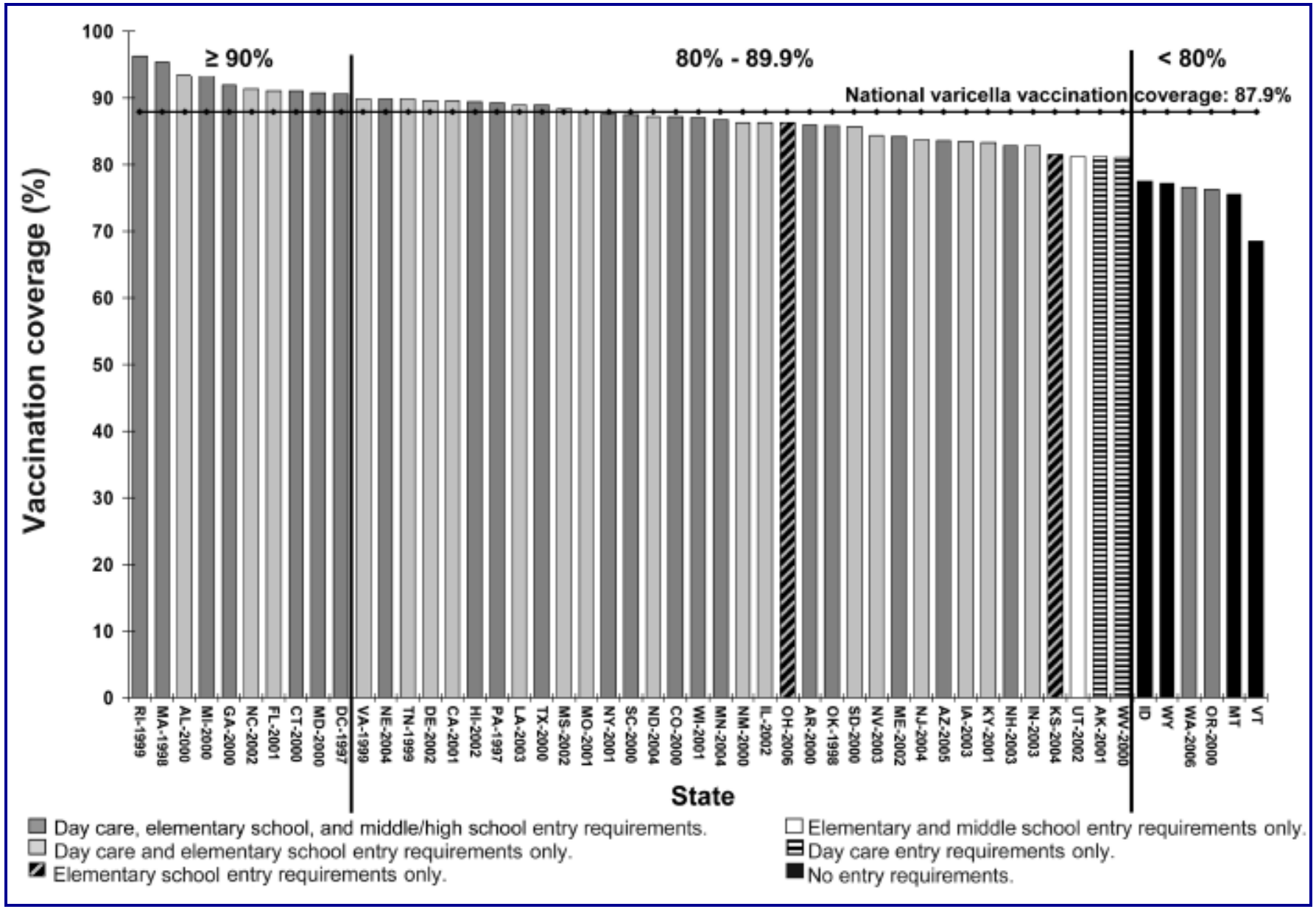


Figure 1. No. of cases and vaccination coverage, Antelope Valley, California *(A)*, and West Philadelphia, Pennsylvania *(B)*, 1995–2005. Boxes with arrows indicate when varicella vaccination requirements for child care (CC), kindergarten (K), and sixth grade (G6) entry went into effect.

Estimated national and state varicella vaccination–coverage, children 19–35 months of age for 2005 and year of implementation of initial entry requirements



Lopez, J Infec Diseases 2008

2018-19 School Year
New York State Immunization Requirements for School Entrance/Attendance[1]

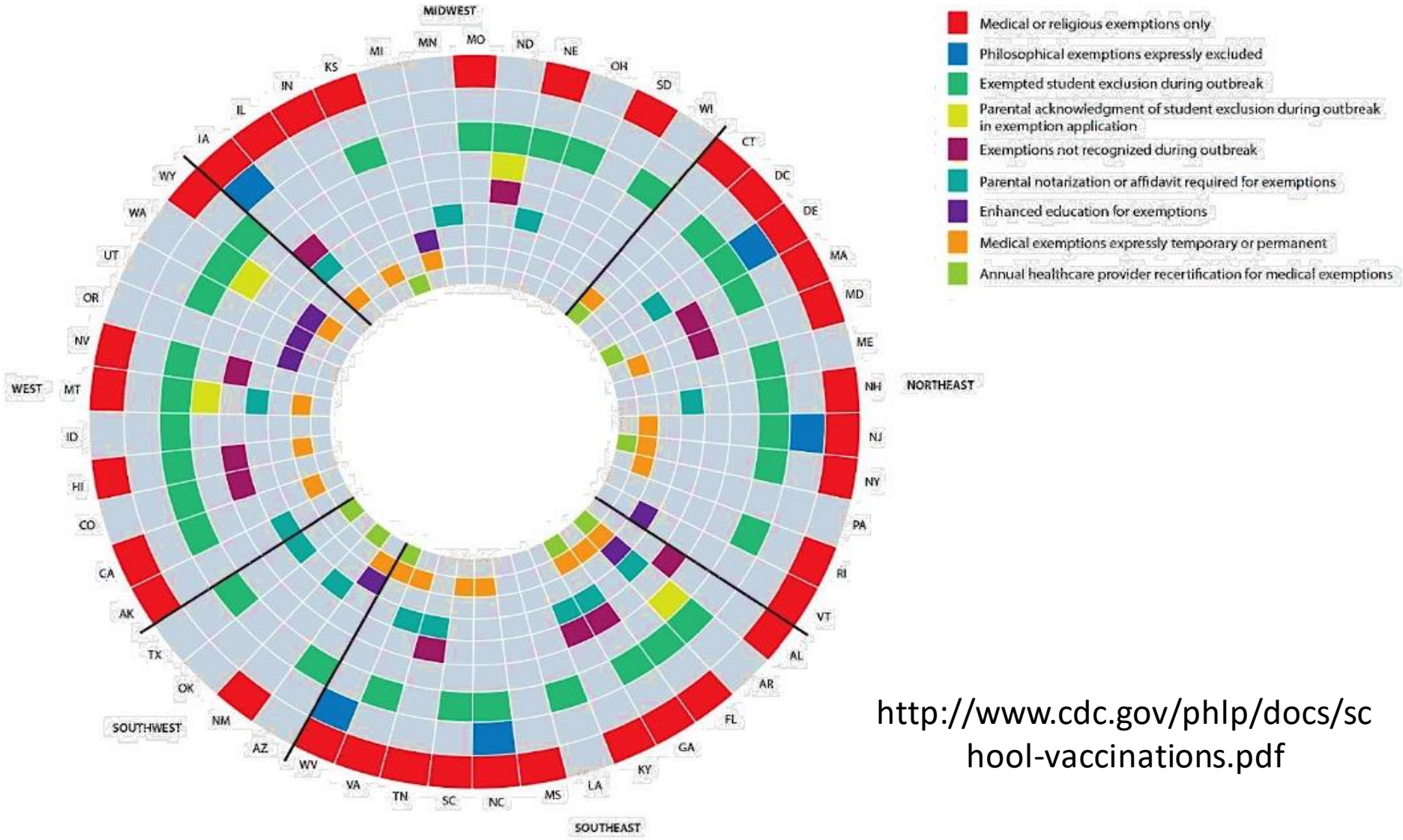
NOTES:
Children in a prekindergarten setting should be age-appropriately immunized. The number of doses depends on the schedule recommended by the Advisory Committee on Immunization Practices (ACIP). For grades pre-k through 10, intervals between doses of vaccine should be in accordance with the ACIP-recommended immunization schedule for persons 0 through 18 years of age. (Exception: Intervals between doses of polio vaccine DO NOT need to be reviewed for grades 5, 11 and 12.) Doses received before the minimum age or intervals are not valid and do not count toward the number of doses listed below. Intervals between doses of vaccine DO NOT need to be reviewed for grades 11 and 12. See footnotes for specific information for each vaccine. Children who are enrolling in grade-less classes should meet the immunization requirements of the grades for which they are age equivalent.

Dose requirements MUST be read with the footnotes of this schedule.

Vaccines	Prekindergarten (Day Care, Head Start, Nursery or Pre-k)	Kindergarten and Grades 1, 2, 3 and 4	Grade 5	Grades 6, 7, 8, 9 and 10	Grades 11 and 12
Diphtheria and Tetanus toxoid-containing vaccine and Pertussis vaccine (DTaP/DTP/Tdap/Td)[2]	4 doses	5 doses or 4 doses if the 4th dose was received at 4 years or older or 3 doses if 7 years or older and the series was started at 1 year or older		3 doses	
Tetanus and Diphtheria toxoid-containing vaccine and Pertussis vaccine booster (Tdap)[3]	Not applicable			1 dose	
Polio vaccine (IPV/OPV)[4]	3 doses	4 doses or 3 doses if the 3rd dose was received at 4 years or older	3 doses	4 doses or 3 doses if the 3rd dose was received at 4 years or older	3 doses
Measles, Mumps and Rubella vaccine (MMR)[5]	1 dose	2 doses			
Hepatitis B vaccine[6]	3 doses	3 doses or 2 doses of adult hepatitis B vaccine (Recombivax) for children who received the doses at least 4 months apart between the ages of 11 through 15 years			
Varicella (Chickenpox) vaccine[7]	1 dose	2 doses	1 dose	2 doses	1 dose
Meningococcal conjugate vaccine (MenACWY)[8]	Not applicable			Grades 7, 8 and 9: 1 dose	Grade 12: 2 doses or 1 dose if the dose was received at 16 years or older
Haemophilus influenzae type b conjugate vaccine (Hib)[9]	1 to 4 doses	Not applicable			
Pneumococcal Conjugate vaccine (PCV)[10]	1 to 4 doses	Not applicable			

https://www.health.ny.gov/publications/2370.pdf

State School Immunization Requirements and Vaccine Exemption Laws



http://www.cdc.gov/phlp/docs/school-vaccinations.pdf

National Vaccine Injury Compensation Program http://www.hrsa.gov/vaccinecompensation/

- Enacted in 1986
  - Went into effect in 1988
  - Amended in 1989……
- "no-fault" alternative to the traditional tort system for resolving certain vaccine injury claims
  - Petitioners must file with NVICP prior to filing suit in the courts
  - Original Vaccines covered:
    - diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio.

Vaccine Injury Compensation Trust Fund

- Funds the National Vaccine Injury Compensation Program (VICP) to compensate vaccine-related injury or death claims for covered vaccines administered on or after October 1, 1988.
- $0.75 excise tax on each dose of vaccine purchased:
  - Tax on a dose of trivalent influenza vaccine is $0.75 because it prevents one disease
  - Tax on a dose of MMR is $2.25 because prevents three diseases.
- Taxable vaccines are those recommended by the CDC for routine administration to children.
- Dept. of Treasury collects the excise taxes, oversees and manages the investing activities for the Trust Fund.
- January 31, 2014, the balance was nearly $5.7 billion.

http://www.hrsa.gov/vaccinecompensation/index.html

Review of Adverse Effects of Vaccines

- HRSA contracts with Institute of Medicine (IOM) to review evidence regarding adverse health events associated with vaccines covered by the Vaccine Injury Compensation Program.

- http://www.hrsa.gov/vaccinecompensation/vaccinetable.html

National Childhood Vaccine Injury Act, Vaccine Injury Table

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2-28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above	Not applicable.

National Childhood Vaccine Injury Act, Vaccine Injury Table

	which illness, disability, injury, or condition arose within the time period prescribed	
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period	Not applicable.

National Childhood Vaccine Injury Act, Vaccine Injury Table

	prescribed.	
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines	No Condition Specified	Not applicable.
X. Varicella vaccine	No Condition Specified	Not applicable.
XI. Rotavirus vaccine	No Condition Specified	Not applicable.
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable.
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable.
XV. Meningococcal vaccines	No Condition Specified	Not applicable.
XVI. Human papillomavirus (HPV) vaccines	No Condition Specified	Not applicable.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage *	No Condition Specified	Not applicable.

Adjudications[1]

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	121	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	265	1,370	1,635
FY 2012	261	2,439	2,700
FY 2013	366	627	993
FY 2014	357	167	524
FY 2015	131	33	160
Total	3,941	9,867	13,804

[1]Generally, petitions/claims are not adjudicated in the same fiscal year as filed. On average, it takes 2-3 years to adjudicate a petition/claim after it is filed.

National Vaccine Injury Compensation Program Post-1988 Statistics Report as of February, 2015

Vaccine(s)	Filed			Compensated	Dismissed
	Injury	Death	Total		
DT	69	9	78	24	51
DTaP	374	80	454	179	203
DTaP-Hep B-IPV	62	24	86	30	34
DTaP-HIB	10	1	11	4	3
DTaP-IPV-HIB	24	16	40	6	11
DTP	3,286	696	3,982	1,270	2,706
DTP-HIB	20	8	28	4	21
Hep A-Hep B	18	0	18	9	2
Hep B-HIB	8	0	8	4	3
Hepatitis A (Hep A)	65	5	70	27	20
Hepatitis B (Hep B)	618	54	672	241	363
HIB	25	3	28	12	14
HPV	255	12	267	73	85
Influenza	1,704	84	1,788	989	155
IPV	264	14	278	8	267
Measles	143	19	162	55	107
Meningococcal	40	2	42	27	4
MMR	890	57	947	367	502
MMR-Varicella	30	1	31	15	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Nonqualified	85	9	94	1	87
OPV	280	28	308	158	150
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	41	5	46	10	26
Rotavirus	65	1	66	39	17
Rubella	190	4	194	70	123
Td	183	3	186	106	64
Tdap	227	1	228	106	12
Tetanus	97	2	99	43	37
Unspecified	5,411	8	5,419	4	4,749
Varicella	78	7	85	51	20
Grand Total	14,591	1,156	15,747	3,941	9,867

http://www.hrsa.gov/vaccinecompensation/statisticsreports.html#_ftnref1

National Vaccine Injury Compensation Program Post-1988 Statistics Report as of Oct. 19, 2010

Fiscal Year	Non-Autism	Autism	Total
FY 1988	24	0	24
FY 1989	148	0	148
FY 1990	1,492	0	1,492
FY 1991	2,718	0	2,718
FY 1992	189	0	189
FY 1993	140	0	140
FY 1994	107	0	107
FY 1995	180	0	180
FY 1996	84	0	84
FY 1997	104	0	104
FY 1998	120	0	120
FY 1999	410	1	411
FY 2000	161	2	163
FY 2001	193	23	216
FY 2002	184	773	957
FY 2003	155	2,437	2,592
FY 2004	127	1,087	1,214
FY 2005	147	588	735
FY 2006	155	170	325
FY 2007	238	172	410
FY 2008	163	254	417
FY 2009	288	109	397
FY 2010	429	18	447
FY 2011	8	0	8
Total	7,964	5,634	13,598

National Vaccine Injury Compensation Program Post-1988 Statistics Report as of Oct. 19, 2010

	Non-Omnibus Autism Proceeding			Omnibus Autism Proceeding			
Fiscal Year	Compensable	Dismissed	Sub-Total	Compensable*	Dismissed	Sub-Total	Total
FY 1989	9	12	21	0	0	0	21
FY 1990	99	33	132	0	0	0	132
FY 1991	142	447	589	0	0	0	589
FY 1992	166	487	653	0	0	0	653
FY 1993	125	588	713	0	0	0	713
FY 1994	162	446	608	0	0	0	608
FY 1995	160	575	735	0	0	0	735
FY 1996	162	408	570	0	0	0	570
FY 1997	189	198	387	0	0	0	387
FY 1998	144	181	325	0	0	0	325
FY 1999	98	139	237	0	0	0	237
FY 2000	124	104	228	0	0	0	228
FY 2001	84	87	171	0	0	0	171
FY 2002	106	99	205	0	5	5	210
FY 2003	55	78	133	0	21	21	154
FY 2004	62	121	183	0	114	114	297
FY 2005	60	72	132	0	52	52	184
FY 2006	69	81	150	0	110	110	260
FY 2007	83	87	170	0	32	32	202
FY 2008	144	81	225	0	56	56	281
FY 2009	133	45	178	0	185	185	363
FY 2010	154	73	227	1**	203	204	431
Totals	2,530	4,442	6,972	1	778	779	7,751

National Vaccine Injury Compensation Program Post-1988 Statistics Report as of February, 2015

Awards Paid[1]

Fiscal Year	Compensated[2]			Dismissed		Interim Fees		Total Outlays
	# of Awards	Petitioners' Award Amount	Attorneys' Fees/ Cost Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	73	$2,511,313.26	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53

National Vaccine Injury Compensation Program Post-1988 Statistics Report as of February, 2015

Awards Paid[1]

Fiscal Year	Compensated[2]			Dismissed		Interim Fees		Total Outlays
	# of Awards	Petitioners' Award Amount	Attorneys' Fees/ Cost Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	# of Payments to Attorneys	Attorneys' Fees/ Costs Payments	
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,637,927.73
FY 2013	375	$254,666,326.70	$13,333,179.53	703	$6,970,278.84	50	$1,454,851.74	$276,424,636.81
FY 2014	365	$202,084,196.12	$11,973,575.82	505	$8,801,345.79	38	$2,493,460.73	$223,352,578.46
FY 2015	177	$83,067,135.53	$4,474,812.40	45	$1,245,066.01	19	$1,044,486.97	$89,831,500.91
Total	3941	$2,885,038,650.06	$121,636,170.55	4925	$65,353,100.74	224	$18,752,260.08	$3,090,780,181.43

Autism Proceedings
U.S. COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

- Autism Test Case Theories
  - The Petitioners' Steering Committee (PSC) originally announced that it would advance 3 different theories of "general causation"
  - The Office of Special Masters (OSM) assigned three Special Masters to resolve the autism cases.
  - The OSM instructed the PSC to designate three "test cases" for each of the three theories, a total of nine test cases.

Autism Proceedings
U.S. COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

The **three theories** of "general causation":

1- MMR vaccines & thimerosal-containing vaccines can combine to cause autism

2 - Thimerosal-containing vaccines can alone cause autism, and

3 - MMR vaccines alone can cause autism

- **The PSC chose not to present the 3rd theory since evidence pertaining to that theory was largely presented in the 1st theory test cases.**

http://www.uscfc.uscourts.gov/node/5026

1st Theory: MMR vaccines & thimerosal-containing vaccines can combine to cause autism

- Hearings were conducted in the three "test cases"
  - **June, 2007:** Special Master George Hastings presided over ***Cedillo v. HHS***
  - **October, 2007:** Special Master Patricia Campbell-Smith presided over ***Hazlehurst v. HHS***
  - **November, 2007**: Special Master Denise Vowell presided over ***Snyder v. HHS***

1st Theory: *Cedillo v. HHS*

- December 20, 1995, at 15 months of age, Michelle received an **MMR vaccination**
  - Well until then
  - 2 months of age: fix her eyes, follow a moving object, startled in response to a loud noise.
  - One year: spoke a few words, crawled on her knees, and pulled herself to stand.
  - 16 -18 months: began walking
  - Prior vaccinations:
    - **3 Hep B, DTP, Hib, Polio**, Varicella, **some containing thimerosal**
- One week post MMR: rash & fever to 105° F
  - Jan. 6, 1996: fever, antibiotics/ post-nasal drip
- 18 months of age: "seemed to be hearing less"
  - **DTP & Hib vaccinations**, both contained thimerosal

1st Theory: *Cedillo v. HHS*

- April 1997: progressive developmental delay
- July, 1997: severe autism, profound mental retardation
- 1999-2000: significant gastrointestinal problems/ chronic diarrhea, GE-reflux, erosive esophagitis, fecal impaction
- 2000-2002: multiple endoscopy samples sent to Unigenetics Laboratory in Dublin, Ireland: “measles virus detected”

1st Theory: *Cedillo v. HHS*

- **Initially, the Cedillos asserted …..MMR vaccine caused ….an encephalopathy, a "Table Injury" under the Vaccine Act:**
  - Only need to show that the vaccinee received a vaccine & suffered an injury listed on the Vaccine Injury Table, and that the injury occurred within the prescribed time period on the Table

- **The Cedillos changed their petition to a "causation-in-fact" claim**, alleging that vaccines containing thimerosal, in combination with the MMR vaccine, cause autism.
  - A **"causation-in-fact"** claim does not carry a presumption of causation, placing the burden on the petitioner to prove that the vaccination actually caused the injury in question
  - The petitioner has the burden of proving a ***prima facie case*** *by a* ***preponderance of the evidence****.*

1st Theory: *Cedillo v. HHS*

- For a "causation-in-fact" claim:
  - The petitioner must satisfy the following 3 criteria to establish that the vaccine caused the injury:

    1. A medical theory causally connecting vaccination & injury

    2. A logical sequence of cause and effect showing that the vaccination was the reason for the injury, and

    3. A proximate temporal relationship between vaccination & injury
- If the petitioner satisfies these 3 elements, the burden then shifts to the respondent to show by a preponderance of the evidence that other factors unrelated to the vaccine caused the injury.
- The causation theory ….. must be supported by a reliable scientific or medical explanation.

1st Theory: *Cedillo v. HHS*

- Petitioners argue that Michelle was a normal child for her first 16 months until she experienced the effects of eleven vaccinations containing thimerosal, and the MMR vaccination.

- The Cedillos claim that the ethyl mercury in thimerosal and the MMR vaccine damaged their daughter's immune system, and that due to her immune deficiency, she was unable to clear from her body the measles virus contained in the MMR vaccine.

- Instead, the measles virus persisted and replicated in Michelle's body, causing her to suffer inflammatory bowel disease.

- The Cedillos also contend that the measles virus ultimately entered Michelle's brain, causing inflammation and autism

1st Theory: MMR Vaccines & Thimerosal-containing Vaccines Can Combine to Cause Autism

- **The Special Masters began deciding their cases:**
  - 5,000 pages of transcript
  - ≥ 700 pages of post-hearing briefs
  - 939 medical articles (typical vaccine case, about 10)
  - 50 expert reports & 28 experts testimonies.

- **Decisions issued on February 12, 2009**

Special Master's Decision: Feb. 12, 2009

- **Petitioners failed to demonstrate that:**

  (1) **thimerosal-containing vaccines can harm infant immune systems in general**, or that Michelle Cedillo's own thimerosal-containing vaccinations harmed her immune system:

  Used adult values, not age-related value to assess immune function

  (2) **MMR vaccine can cause autism in general**, or that Michelle Cedillo's own MMR vaccination contributed to her autism

  (3) **MMR vaccine can cause gastrointestinal dysfunction in general**, or that Michelle Cedillo's own MMR vaccination contributed to her gastrointestinal problems, or….

Special Master's Decision: Feb. 12, 2009

- Petitioners failed to demonstrate that:

  (4**) Michelle Cedillo's own MMR vaccination caused her mental retardation** or seizure disorder.

  Furthermore, the Special Master **deemed unreliable the testing Petitioners offered to show the presence of the measles virus** in Michelle Cedillo and other autistic children:

  - Samples not blinded, false positive & negative controls, discordant results, no sequencing of amplification products, etc.

  Evidence concerning the causation of regressive autism combined with gastrointestinal dysfunction in some individuals did not persuasively show either or both conditions to be vaccine-related.

1st Theory: MMR Vaccines & Thimerosal-containing Vaccines Can Combine to Cause Autism

- The **Special Master's** decision is final, unless within 30 days of issuance, a party seeks review from a **Judge of the United States Court of Federal Claims** who reviews the record of the proceedings and either
  - 1) affirms the Special Master's findings & conclusions
  - 2) sets aside any findings of fact and conclusions of law found to be arbitrary, capricious or an abuse of discretion
  - 3) remands the case for further action in accordance with the court's direction.

Review Process

- **March 13, 2009, Petitioners filed a motion for reconsideration**, requesting the Special Master to overturn his February 12, 2009 decision based on new evidence not available at the June 2007 hearing.
  - Special Master Hastings denied the motion on March 16, 2009 because it was not filed within the 21-day period required

- **August 6, 2009: Review from a Judge of the United States Court of Federal Claims upheld the Special Master's decision**
  - While a special master must resolve "close calls" in favor of a petitioner, Special Master Hastings concluded that this "is *not a close case;*" rather, "[t]he overall weight of the evidence is *overwhelmingly contrary* to the petitioners' causation theories."

- The Cedillos appealed to the U.S. Court of Appeals for the Federal Circuits

1st Theory: MMR Vaccines & Thimerosal-containing Vaccines Can Combine to Cause Autism

- The petitioners sought review & in each case, a Judge affirmed the Special Masters' decision.
  - These proceedings are final, unless a party seeks review in the U.S. Court of Appeals for the Federal Circuits within 60 days
    - In two of the three (Cedillo & Hazelhurst), the petitioners appealed to the Federal Circuit:
      - Both appeals were denied Cedillo (8/27/10) & Hazelhurst (5/13/10)
    - In the third case (Snyder), no appeal was filed.
  - Finally, a party may seek review of the Federal Circuit's decision in the **Supreme Court of the United States**

2nd Theory: Thimerosal-containing Vaccines Alone Can Cause Autism

- Hearings in the 3 test cases conducted over three weeks in May – July, 2008 in Wash., D.C.
  - Special Master George Hastings heard **King v. HHS**
  - Special Master Patricia Campbell-Smith heard **Mead v. HHS**
  - Special Master Denise Vowell heard **Dwyer v. HHS**.
  - Extensive post-hearing briefings in July, 2009.
  - The Special Masters' decisions in the three test cases were issued on March 12, 2010

2nd Theory: Thimerosal-containing Vaccines Alone Can Cause Autism

- Thimerosal dissociates into the organomercurial ethylmercury which via the blood, diffuses across the blood-brain barrier to the brain, where it is de-ethylated, becoming inorganic mercury, a form of mercury that persists & provokes a series of detrimental responses that manifest as autism

2nd Theory: Thimerosal-containing Vaccines Alone Can Cause Autism

- **Local neuroinflammatory process**
  - environment of oxidative stress
  - complex cycle of impaired & disrupted chemical processes interfering with brain function, but not causing “gross neurotoxicity” or “neuronal death”
  - “an overabundance of glutamate,” the primary excitatory neurochemical in the brain
  - a persistent state of “over-excitation”
- **A compensatory expression of autistic symptoms**

2nd Theory: Special Masters' Decision

Criterion #1: The Proposed Medical Theory

- Petitioners failed to prove that toxicity of ethyl mercury is equivalent to that of methyl mercury
- Clinical toxicity of methyl mercury is characterized by loss of motor control, which is generally not seen in autism

2nd Theory: Special Masters' Decision

Criterion #1: The Proposed Medical Theory, cont'd

- Petitioners focus on subcellular effects of chronic, low-dose presence of inorganic mercury on glutathione metabolism:
  - Low-dose exposures referenced exceeded exposure dosages attributable to vaccines, by at least an order of magnitude
  - Failed to present reliable evidence showing that either a genetically hypersusceptible population to mercury exposures exists or a mercury efflux disorder exists
  - Relied on in vitro assays & unpublished findings to illustrate the effect of mercury on glutamate metabolism
  - Failed to demonstrate that there was microglial activation leading to neuroinflammation, an overabundance of glutamate, and a chronic state of overexcitation in the brain that symptomatically manifests as autism

2nd Theory: Special Masters' Decision

Criterion #2: The Sequence of Cause and Effect

- Petitioners contend that William's history & test results are consistent with the theory of causation proposed :
  - Short half-life of organic mercury is not consistent with high blood mercury levels almost one year after last thimerosal-containing vaccine
  - Inappropriate use of provoked rather than unprovoked (nonchelated) urine specimens for mercury excretion levels
    - Nonchelated samples were normal
  - Use of non-age corrected lab ranges

2nd Theory: Special Masters' Decision

Criterion #3: The Temporal Association

- Petitioners posit that harm can occur in certain genetically susceptible children, petitioners could not identify the window of neurodevelopmental vulnerability
- Petitioners could not identify the period of time between the deposition of inorganic mercury in the brain and the start of the neuroinflammatory process that was critical to their proposed mechanism of biological harm
- Petitioners' theory of causation relies on evidence that symptoms of autism with regression first appeared after the administration of a full complement of thimerosal-containing vaccines. Without more, petitioners have not shown that the appearance of William's autistic symptoms occurred within a medically acceptable time frame to support a finding that the administered vaccines were causally related to his symptom onset.

2nd Theory: Special Masters' Decision

Conclusion:

- Petitioners' claim that the performed epidemiological studies lack the requisite specificity to detect an association between the receipt of thimerosal-containing vaccines and the allegedly small subset of cases involving autism with clear signs of regression
- Failed to establish that autism with regressive features exists as a distinct phenotype of autism. To the contrary, studies indicate that regression is common in autistic children
- Have not shown either that certain children are genetically hypersusceptible to mercury or that certain children are predisposed to have difficulty excreting mercury
- Have not shown that the inorganic mercury deposited in the brain–in the amount that could be received from a full complement of thimerosal containing vaccines–can cause the effects that petitioners have alleged.
- A normal fish-eating diet by pregnant mothers produces a greater source of inorganic mercury for deposition in the brain than thimerosal-containing vaccines
- The mechanism of chronic cellular dysfunction that petitioners have hypothesized cannot be maintained without inducing progressive neurodegenerative disease that leads to death, and autism is not a progressive neurodegenerative disease

2nd Theory: Special Masters' Decision

- Petitioners' theory of vaccine-related causation is scientifically unsupportable.
- In the absence of a sound medical theory causally connecting William's received vaccines to his autistic condition, the undersigned cannot find the proposed sequence of cause and effect to be logical or temporally appropriate.
- Having failed to satisfy their burden of proof under the articulated legal standard, petitioners cannot prevail on their claim of vaccine-related causation. Petitioners' claim is dismissed
  - No appeals have been filed

Bruesewitz v. Wyeth
U.S. Supreme Court Oct. 2010

- Whether the federal regime "preempts" state tort law. In other words: to what degree does the federal law take away plaintiffs' ability to sue for damages in state court.

- 18-year-old woman, Hannah Bruesewitz, who suffered seizures when she was 6 months old and subsequently suffered developmental problems, her parents say, after receiving a type of vaccine that is no longer sold.

- Question of whether Congress intended to bar lawsuits against vaccine manufacturers based on so-called **design defect** claims.
- a **vaccine design defect** claim essentially asserts that the manufacturer should have sold a different, safer, vaccine.
- Some vaccination cases have pointed to design defects whereby a manufacturer produced a vaccination that presented higher risk for injury - even as the very same manufacturer had designs available to them that presented less risk for injury

Bruesewitz v. Wyeth
U.S. Supreme Court Oct. 2010

- **February 22, 2011 in a 6-2 decision, the U.S. Supreme Court affirmed the ruling of the U.S. Court of Appeals for the Third Circuit in favor of Pfizer's subsidiary Wyeth**, in Bruesewitz v. Wyeth. The Third Circuit determined that the **National Childhood Vaccine Injury Act prevents civil suits against manufacturers of FDA-approved childhood vaccines** based on a claim that a particular vaccine should have been designed differently.

- No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings

Investigative Reporting: Wakefield Saga

- Time course:
  - 1998: Wakefield's Lancet paper
  - 2004: Deer's 1st presentation of allegations of misconduct & Lancet's rejection of those allegations
  - 2004: Co-authors' retraction of "interpretation" of findings implying a link between MMR & autism, but….
  - 2008: Hornig, PLoS one fails to replicate findings
  - 2010: U.K. General Medical Council's Fitness to Practise Panel
  - 2010: Lancet retracts the Wakefield paper:
    - "it has become clear that several elements of the 1998 paper by Wakefield et al are incorrect, contrary to the findings of an earlier investigation. In particular, the claims in the original paper that children were "consecutively referred" and that investigations were "approved" by the local ethics committee have been proven to be false. Therefore we fully retract this paper from the published record."

Investigative Reporting: Wakefield Saga

- 2010-2012: Brian Deer's investigative series in the British Medical Journal
- Witch hunt vs. uncovering fraud?
- Fraud vs. scientific misconduct?
- Long-term consequences?

New Vaccine Media Coverage

Jimmy Kimmel, Feb. 2015
https://www.youtube.com/watch?v=QgpfNScEd3M