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STATE OF VERMONT
SENATE COMMITTEE

Senate Committee on Health and Welfare

AGENDA

Room 17

January 31, 2012 - February 3, 2012

Tuesday, January 31, 2012

9:30 AM **Senate Floor**

- **Chairs Meeting**

- **Public Oversight Commission**

Repeal of Commission

Trinka Kerr, Health Care Ombudsman

David Martini, General Counsel, Department of Banking, Insurance, Securities & Health Care Administration

- **S. 222 - An act relating to cost-sharing for employer-sponsored insurance assistance plans**

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

Mark Larson, Commissioner, Department of Vermont Health Access

Peter Sterling, Executive Director, Vermont Campaign for Health Care Security

Trinka Kerr, Health Care Ombudsman

Wednesday, February 01, 2012

9:00 AM **Governor's Appointment**

Confirmation of Commissioner of the Department of Mental Health

Patrick Flood, Commissioner, Department of Mental Health

9:30 AM **S. 209 - An act relating to naturopathic physicians**

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

Lorilee Schoenbeck, N.D., Mountain View Natural Medicine

Craig Jones, Director, Vermont Blueprint for Health

Hunt Blair, Deputy Commissioner, Department of Vermont Health Access (DVHA)

David Martini, General Counsel, Department of Banking, Insurance, Securities & Health Care Administration

Madeleine Mongan, Vice-President, Vermont Medical Society

10:30 AM **S. 223 - An act relating to extending health insurance coverage for autism spectrum disorders**

Katie McLinn, Legislative Counsel, Office of Legislative Council

Fred Volkmar, MD, Director of the Child Center Study, Yale University School of Medicine

Judith Ursitti, Regional Director, National Autism Speaks Organization

Amy Cohen, Clinical Director Autism Spectrum Disorder, Howard Center

Martha Frank, Family Support Consultant, Vermont Family Network

5:00-7:00 PM **H. 559 - An act relating to health care reform implementation**

Public Hearing- Definition of a small employer- Joint with House Health Care, Room 11

Thursday, February 02, 2012

9:00 AM **S. 200 - An act relating to the reporting requirements of health insurers**

Katie McLinn, Legislative Counsel, Office of Legislative Council

Cassandra Gekas, Health Care Advocate, VPIRG

10:00 AM **S. 199 - An act relating to immunization exemptions and the immunization pilot program**

Committee Discussion

10:10 AM **S. 222 - An act relating to cost-sharing for employer-sponsored**

insurance assistance plans

Committee Discussion

10:20 AM **S. 223 - An act relating to extending health insurance coverage for autism spectrum disorders**

Committee Discussion

10:25 AM **S. 191 - An act relating to rational treatment of chronic pain**

Committee Discussion

- **S. 242 - An act relating to prescribing a controlled substance**

Committee Discussion

10:30 AM **S. 197 - An act relating to hospital-based outpatient fees**

Committee Discussion

10:45 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Committee Discussion

11:15 AM **S. 83 - An act relating to renal dialysis patient safety**

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

Geri Streeter, RN

Christine Fasset, Certified Hemodialysis Technician

Sam Heffernan, RN, Central Vermont Hospital

11:45 AM **Developmental Disabilities Awareness**

Kaiya Andrews, Green Moutain Self Advocates

Jessica Sanville, Member, East Haven

Craig Davis, Member, Middlebury, VT

Lisa Maynes, President, Vermont Development Disability Council

Friday, February 03, 2012

9:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Committee Discussion

Rebecca Heintz, Deputy Commissioner, Department of Mental

Health

Nick Nichols, Policy Director, Department of Mental Health

9:45 AM **S. 236 - An act relating to health care practitioner signature authority**

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

Deborah Wachtel, Vermont Nurse Practitioners Association

Linda Davidson, Executive Director, Nursing Board

Madeleine Mongan, Vice-President, Vermont Medical Society

10:30 AM **S. 198 - An act relating to a lupus advisory panel within the department of health**

Katie McLinn, Legislative Counsel, Office of Legislative Council

Dawn Philbert, Director of Public Health Policy, Department of Health

Kathleen Arntsen, Patient Advocate, Lupus Research Institute

11:00 AM **S. 199 - An act relating to immunization exemptions and the immunization pilot program**

Patsy Kelso, State Epidemiologist

Josette Silvers, Parent, North Middlesex

Dr. Andrea Regan, Vermont Academy of Family Physicians

Dr. Jerry Larrabee, Medical Director, University Pediatrics at Fletcher Allen

Kristen Connolly, MD, University Pediatrics at Fletcher Allen

Katie Murphy, Vermont Pharmacists Association

Joan Kahn, Parent

Rep. George Till

Martha Isreal, School Nurse

Dexter Lefavour, Parent, Middlesex

Dawn Richardson, Director of Advocacy, National Vaccine Information Center

Jennifer Stella, Mountain Valley Wellness

LUCY S.199 1

REBECA SAMANCI 2/3/12

My little granddaughter Lucy was vaccinated for HIB a month ago. She got HIB anyway and was 2 weeks in the PICU on a ventilator, fed her mother's breast milk through a tube and getting antibiotics and all kinds of sedatives intravenously. Now she is off the ventilator and is being slowly withdrawn from the drugs She is only 5 months old.

My daughter has been through hell. I saw her sobbing and distraught. Thank God the doctors saved the baby's life. That is what they are good at.

So the vaccine provided no protection. Further, I think that it harmed her. Something took down the immune system of this radiantly healthy baby. Vaccines can harm children. If not, why is there a huge federally funded vaccine injury compensation program?

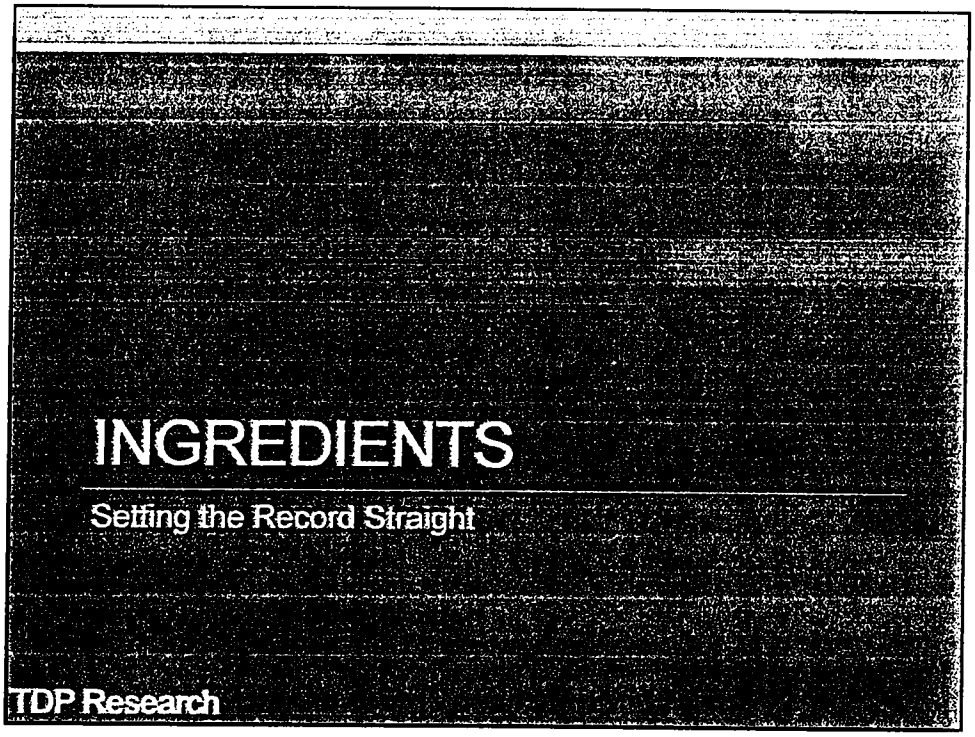
My children are now under constant, and I think rather unseemly, pressure to give Lucy even more vaccinations. Now, if you pass this bill, they would have to, even if they fear for their child's life and health.

The pro vaccine people simply have a philosophical belief that every body should be vaccinated for everything no matter what. And if I am to believe the research sent to me by the National Vaccination Information Center, the claim that Vermont has one of the lowest vaccination rates in the country is a bunch of claptrap.

The law should not force people to put aside their personal beliefs just because they conflict with the beliefs of some other group that just happens to be able to afford a lobbyist.

DR. PEET 2/3/12

HOW SAFE ARE VACCINES?



Vaccines Containing Mercury

Food and Drug Administration and CDC (2011)

Disease	Product	Manufacturer	Amount Used
Haemophilus b Conjugate	ActHIB	Sanofi Pasteur	<0.3 mcg
Influenza A (H1N1)	None	CSL Limited	24.5mcg/dose in multi-dose vials
Influenza A (H1N1)	None	ID Biomedical	25mcg/dose
Influenza A (H1N1)	None	Novartis	<1mcg/dose in single dose vials, 25mcg/dose in multi-dos vials
Influenza A (H1N1)	None	Sanofi Pasteur	25mcg/dose in multi-dose
Influenza (H5N1)	Influenza Virus Vaccine, H5N1	Sanofi Pasteur	50ug/dose
Influenza A & B	Afluria	CSL Limited	24.5mcg/dose in multi-dose vials
Influenza A & B	FluLaval	ID Biomedical	25mcg/dose
Influenza A & B	Fluvirin	Novartis	<1mcg/dose in single dose vials, 25mcg/dose in multi-dos vials
Influenza A & B	Fluzone and Fluzone High-Dose	Sanofi Pasteur	25 mcg/dose in multi-dose
Japanese Encephalitis	JE-Vax	Research Foundation for Microbial Diseases	0.007%/dose
Meningococcal	Menomune	Sanofi Pasteur	In multi-dose only
Tetanus & Diphtheria	None	MassBiologics	<0.3mcg/dose in production
Tetanus & Diphtheria	DECAVAC	Sanofi Pasteur	<0.3mcg/dose in production
Tetanus	None	Sanofi Pasteur	25ug/dose
Tetanus Adsorbed	None	Sanofi Pasteur	25ug/dose

The Danish Study is Now Being Questioned

Kreesten M. Madsen, MD*, Marlene B. Lauritsen, MD‡, Carsten B. Pedersen, Msc§, Poul Thorsen, MD, PhD*, Anne-Marie Plesner, MD, PhD¶, Peter H. Andersen, MD¶, Preben B. Mortensen, MD, DMSc¶

(Oct. 25, 2011 /PRNewswire-USNewswire)

- "One coauthor, from Aarhus University, Denmark, was aware of the omission and alerted CDC .
- One of the authors of the study, Dr. Poul Thorsen, was indicted this year in Atlanta for embezzlement in relation to the the $11 million CDC autism grant for that study, and reports have now come out exposing what may be be omissions and errors in the study's conclusions.
- Danish autism rates did not go up, in fact, they went down and have continued to decline since removing thimerosal.

Aluminum adjuvants in vaccines cause autoimmune weakness

Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity in pediatric populations. Lupus. 2011;21(2):223-230

Experimental evidence shows that simultaneous administration of as little as two to three immune adjuvants can overcome genetic resistance to autoimmunity.

In some developed countries, by the time children are 4 to 6 years old, they will have received a total of 126 antigenic compounds along with high amounts of aluminum (Al) adjuvants through routine vaccinations.

According to the US Food and Drug Administration, safety assessments for vaccines have often not included appropriate toxicity studies because vaccines have not been viewed as inherently toxic.

Vaccines Containing Aluminum Based Compounds

Food and Drug Administration, 2011

Disease	Product	Manufacturer
Diphtheria & Tetanus Toxoids Adsorbed	None	Sanofi Pasteur
Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed	Tripedia	Sanofi Pasteur
Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed	Infanrix	GlaxoSmithKline
Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed	DAPTACEL	Sanofi Pasteur
Diphtheria & Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus	Pediarix	GlaxoSmithKline
Diphtheria & Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus	KINRIX	GlaxoSmithKline
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate	Pentacel	Sanofi Pasteur
Haemophilus b Conjugate & Hepatitis B	COMVAX	Merck
Hepatitis A, Inactivated	Havrix	GlaxoSmithKline
Hepatitis A, Inactivated	VAQTA	Merck
Hepatitis A, Inactivated & Hepatitis B	Twinrix	GlaxoSmithKline
Hepatitis B	Engerix-B	GlaxoSmithKline

Vaccines Containing Aluminum Based Compounds (cont.)

Food and Drug Administration, 2011

Disease	Product	Manufacturer
Hepatitis B	RECOMBIVAX HB	Merck
Human Papillomavirus Quadrivalent	Gardasil	Merck
Human Papillomavirus Bivalent	Cervarix	GlaxoSmithKline
Japanese Encephalitis	IXIARO	Intercell Biomedical
Pneumococcal 7-valent	Prevnar	Wyeth
Pneumococcal 13-valent	Prevnar 13	Wyeth
Tetanus & Diphtheria	None	MassBiologics
Tetanus & Diphtheria	DECAVAC	Sanofi Pasteur
Tetanus	None	Sanofi Pasteur
Tetanus Adsorbed	None	Sanofi Pasteur
Tetanus, Reduced Diphtheria & Acellular Pertussis	Adacel	Sanofi Pasteur
Tetanus, Reduced Diphtheria & Acellular Pertussis	Boostrix	GlaxoSmithKline

Aluminum Is Not Without Risks (New Study, cont.)

Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity in pediatric populations. Lupus. 2011;21(2):223-230

STUDY REPORTED THESE CONCLUSIONS:

- Taken together, these observations raise plausible concerns about the overall safety of current childhood vaccination programs. When assessing adjuvant toxicity in children, several key points ought to be considered:
  - infants and children should not be viewed as "small adults" with regard to toxicological risk as their unique physiology makes them much more vulnerable to toxic insults;
  - in adult humans Al vaccine adjuvants have been linked to a variety of serious autoimmune and inflammatory conditions (i.e., "ASIA"), yet children are regularly exposed to much higher amounts of Al from vaccines than adults;

CONTINUED: NEW STUDY CONCLUSIONS

Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity in pediatric populations. Lupus. 2011;21(2):223-230

it is often assumed that peripheral immune responses do not affect brain function. However, it is now clearly established that there is a bidirectional neuro-immune cross-talk that plays crucial roles in immunoregulation as well as brain function. In turn, perturbations of the neuro-immune axis have been demonstrated in many autoimmune diseases encompassed in "ASIA" and are thought to be driven by a hyperactive immune response; and

the same components of the neuro-immune axis that play key roles in brain development and immune function are heavily targeted by Al adjuvants. In summary, research evidence shows that increasing concerns about current vaccination practices may indeed be warranted. Because children may be most at risk of vaccine-induced complications, a rigorous evaluation of the vaccine-related adverse health impacts in the pediatric population is urgently needed.

Some vaccines Contain sodium borate

Gardasil (produced by Merck) package insert.

Sodium borate salts are classic alkaline buffers in detergent formulations, with pH determined principally by the acid:base ratio, i.e. $[H^+]=Ka[H_3BO_3] / [B(OH)^-_4]$. (www.borax.com, accessed 2012)

What are the ingredients in GARDASIL?
The ingredients are proteins of HPV Types 6, 11, 16, and 18, amorphous aluminum hydroxyphosphate sulfate, yeast protein, sodium chloride, L-histidine, polysorbate 80, sodium borate and water for injection.

This leaflet is a summary of information about GARDASIL. If you would like more information, please talk to your health care provider or visit www.gardasil.com.

Manufactured and Distributed by: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ 08889, USA

Issued April 2011

Sodium Borate Has Extreme Risks

Asia One News, "China's state council seeks stricter ban on additives", April 22, 2011

Food and Drug Administration, 2012

"Sodium borate, a white powder consisting of soft colorless crystals that dissolves easily in water, is widely used in producing detergents, cosmetics and enamel glazes and to make buffer solutions in biochemistry.

But health authorities (in China) have banned it as a food additive, noting that 5 grams of sodium borate can kill a child."

Sodium Borate, also known as E285 and Borax, is banned as a food additive by the FDA in the United States, stating that it is, "***Illegal for use in foods incl. wax ctg for fruits and vegetables.***"

Virginia Legislature Is Moving To Repeal Requiring Gardasil Vaccinations

Washington Post, "Va. House passes bill to repeal law requiring HPV vaccination for young girls," January 27, 2012

Talwar, Pia, "Bills would repeal HPV vaccine requirement," Loudoun Times, January 23, 2012

- An early version of the Virginia house bill contained a clause addressing liability issues "if a female who is inoculated with the HPV vaccine becomes incapable of naturally conceiving a healthy child carried to live birth or experiences impaired fertility as a result of the HPV vaccine".
- Legislators got that idea because the vaccine contains Polysorbate 80, which is linked to infertility in mice. The Merck HPV vaccine also contains sodium borate which is a common roach killer in each of its three doses.
- The National Library of Medicine (NLM) of the National Institutes of Health notes of sodium borate that it "is now known to be a dangerous poison, it is no longer commonly used in medical preparations." That was published in 2005.
- Yet the FDA in 2006 approved the Merck vaccine with this "dangerous poison" to be "commonly used" in these vaccinations.
- The symptoms of sodium borate poisoning according to the NLM citation include many of the side effects being reported after less than six months of the vaccine usage. These include convulsions, collapse, and seizures that include twitching of facial muscles, arms, hands, legs, and feet.

HISTORICAL DECLINE IN DISEASES REPORTED BY CDC

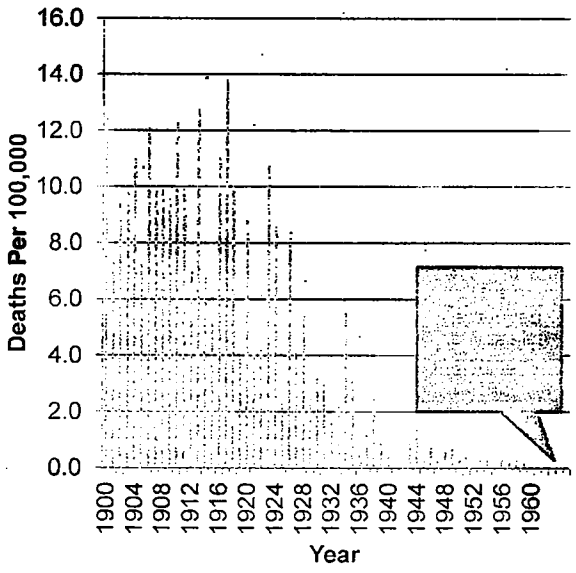
Two Stark Examples

TDP Research

Historical Death Rates for Measles

All data is from the United States Statistical Abstracts. The death rate was so low, that the U.S. Government stopped reporting the data. This was three years before Merck developed the Measles vaccine.

US Census Bureau (1900-1963)



Measles Is Rarely Fatal in United States

Palevsky, Lawrence B. MD, FAAP, DABHM, "Vaccinations: An Open Dialogue & Discussion, 2003

Parents and scientists have questioned the need for the measles vaccine. Measles infections can be beneficial for the maturity of a child's neurological and immune system.

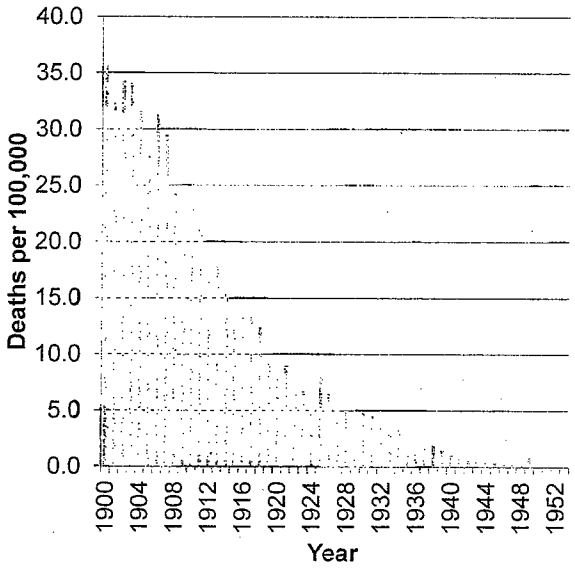
Measles is a benign disease leaving only 3 in 10,000,000 deaths by 1957, 6 years before the introduction of the first measles vaccine.

Even serious neurological outcomes (SSPE—subacute sclerosing panencephalitis) from the illness are rare and would be rarer if the right nutritional treatments and preventive measures were taken before, during and after the illness. By 1960, the incidence of SSPE was 61 cases per 10,000,000 measles infections.

Historical Death Rate for Typhoid

All data is from the United States Statistical Abstract. There never was an active vaccine program against Typhoid.

U.S. Census Bureau (1900-1955)



FETAL CELLS IN VACCINES

New concerns about safety

TDP Research

Change Points In Autism Rates Linked to Vaccines

McDonald, M. E., & Paul, J. F. (2010). Timing of Increased Autistic Disorder Cumulative Incidence. *Environmental Science Technology*, 2112-2118.

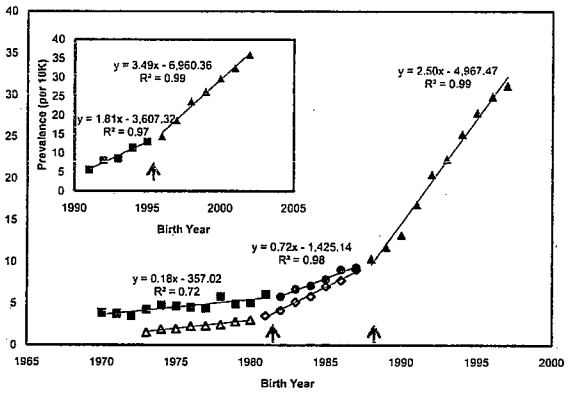
Ard, A., Bwabye, S., Koyama, K., Doan, N., LaMadrid, M. A., & Deisher, T. A. (2010). Computational Detection of Homologous Recombination in Hotspots in X-Chromosome Autism-Associated Genes. (University of Portland, Portland OR, Seattle University, Seattle, WA, & Sound Choice Pharmaceutical Institute, Seattle, WA. Eds.)

EPA scientists M.E. McDonald and J.F. Paul show that there is statistically significant link with the use of the MMR-II vaccine and the increase in the autism rate.

Additional scientists link the use of Varicella (chicken pox vaccine) to the increase in the autism rate.

Graph Showing the Link Between Autism and Fetal Cell Based Vaccines

Ard, A., Bwabye, S., Koyama, K., Doan, N., LaMadrid, M. A., & Deisher, T. A. (2010). Computational Detection of Homologous Recombination in Hotspots in X-Chromosome Autism-Associated Genes. (University of Portland, Portland OR, Seattle University, Seattle, WA, & Sound Choice Pharmaceutical Institute, Seattle, WA, Eds.)



Arrows point to changepoint years obtained using hockey-stick analysis. Filled points are from California (CA) Department of Developmental Services (DDS), open points are from Department of Education (DOE), 19 year olds. Inset is adapted from CA DDS data in Schechter & Grether (2008).

WI-38

L. Hayflick and P.S. Moorhead, "The Serial Cultivation of Human Diploid Cell Strains," Experimental Cell Research 25 (1961), pp. 585-621.

L. Hayflick, "The Limited In Vitro Lifetime of Human Diploid Cell Strains," Experimental Cell Research 37 (1965), pp. 614-635.

E.L. Buescher and W.C. Cockburn (chairs), "Gamma Globulin Prophylaxis; Inactivated Rubella Virus, Production and Biologics Control of Live Attenuated Rubella Virus Vaccines," American Journal of Diseases of Children 118 (1969), p. 378.

Leonard Hayflick and Paul Moorhead, two scientists from the Wistar Institute of Anatomy and Biology, wrote a major work in 1961 discussing their discovery of fetal cell lines. Hayflick followed up this work in 1965 with his team's discovery of the WI-38 strain.

Hayflick and his team developed one such strain, and called it WI-38. His tissue was taken from the lungs of a 3-month-old female fetus. This was confirmed in a panel discussion published in 1969. During this conference, Dr. Stanley Plotkin explained,

"This fetus was chosen by Dr. Sven Gard, specifically for this purpose. Both parents are known, and unfortunately for the story, they are married to each other, still alive and well, and living in Stockholm presumably. The abortion was done because they felt they had too many children. There were no familial diseases in the history of either parent, and no history of cancer specifically in the families; that is, the maternal or paternal sides."

MRC-5

J.P. Jacobs, C.M. Jones, and J.P. Baille, "Characteristics of a Human Diploid Cell Designated MRC-5," Nature 227 (1970), pp. 168-170.

- A team of scientists from the National Institute for Medical Research (NIMR) developed another major cell strain with their discovery of the MRC-5 line.
  - The NIMR team explained their fetus as such,
    - "We have developed another strain of cells, also derived from foetal lung tissue, taken from a 14-week male foetus removed for psychiatric reasons from a 27 year old woman with a genetically normal family history and no sign of neoplastic disease both at abortion and for at least three years afterwards."

These Fetal Cells Were Developed for Vaccines

- L. Hayflick and P.S. Moorhead, "The Serial Cultivation of Human Diploid Cell Strains," Experimental Cell Research 25 (1961), pp. 585-621.
- J.P. Jacobs, C.M. Jones, and J.P. Baille, "Characteristics of a Human Diploid Cell Designated MRC-5," Nature 227 (1970), pp. 168-170.

- In discussing the possibilities for such research, Hayflick and Moorhead wrote about the virus susceptibility of the human cell strains. In their work, they list 31 separate viruses including those more familiar such as measles, polio, varicella, rabies, herpes simplex, and influenza.
- The NIMR wrote in their findings that they were able to, "duplicate using polioviruses, several ECHO viruses, arboviruses, adenoviruses, rhinoviruses and herpes viruses, and those of vaccinia, measles, rubella, and Coxsackie A9.".

Warnings From The Past

Buescher, E. L., & Cockburn (chairs), W. C. (1969). Gamma Globulin Prophylaxis; Inactivated Rubella Virus, Production and Biologics Control of Live Attenuated Rubella Virus Vaccines. *American Journal of Diseases of Children*, 372-386.

Past warnings about the use of fetal cells were theorized by Kevin McCarthy, the developer of the measles vaccine, when he stated that one of two things he worried about "…in regard to WI-38 cell substrate," and highlighting, "…the possibility of there being human genetic material passed over into the vaccine."

Vaccines Containing Fetal Cells

All Data from the Food Drug Administration (2011)

Disease	Product	Manufacturer	Human Cell
Diphtheria, Tetanus, Pertussis, Poliovirus and Haemophilus b	Pentacel	Sanofi Pasteur	MRC-5
Hepatitis A	Havrix	GlaxoSmithKline	MRC-5
Hepatitis A	VAQTA	Merck	MRC-5
Hepatitis A and Hepatitis B	Twinrix	GlaxoSmithKline	MRC-5
Measles, Mumps, and Rubella	M-M-R II	Merck	WI-38
Measles, Mumps, Rubella, and Varicella	ProQuad	Merck	WI-38 & MRC-5
Rabies	IMOVAX	Sanofi Pasteur	MRC-5
Rubella	Meruvax II	Merck	WI-38
Varicella (Chickenpox)	Varivax	Merck	WI-38 & MRC-5
Zoster (Shingles)	Zostavax	Merck	MRC-5

WI-38 and MRC-5 are still for sale

Product Description

Cell Biology

ATCC® Number:	CCL-75™	Order this Item	
Designations:	WI-38		
Depositors:	L Hayflick		
Biosafety Level:	1		
Shipped:	frozen		
Medium & Serum:	See Preparation		
Growth Properties:	adherent		
Organism:	*Homo sapiens*		
Morphology:	fibroblast		
Source:	Organ: lung Disease: normal Cell Type: fibroblast		
Permits/Terms:	In addition to the MTA mentioned above, other ATCC and/or regulatory permits may be required for the transfer of this ATCC material. Anyone purchasing ATCC material is ultimately responsible for obtaining the permits. Please click here for information regarding the specific requirements for shipment to your location.		
Applications:	Assay Transfection host Virus/cell typing		
Virus Susceptibility:	Reticular cytomatrix, Glasgow (Indiana); Herpes simplex virus Parainfluenza Jinx		

Price: $279.00

Related Links ▸

- NCBI Entrez Search
- How to Order
- Frequently Asked Questions
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- Technical Support
- Related Cell Culture Products

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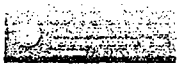
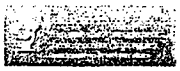
- Product Information Sheet





VACCINES AND EFFECTS ON LONG TERM LEARNING

One Must Look Past Immediate Effects

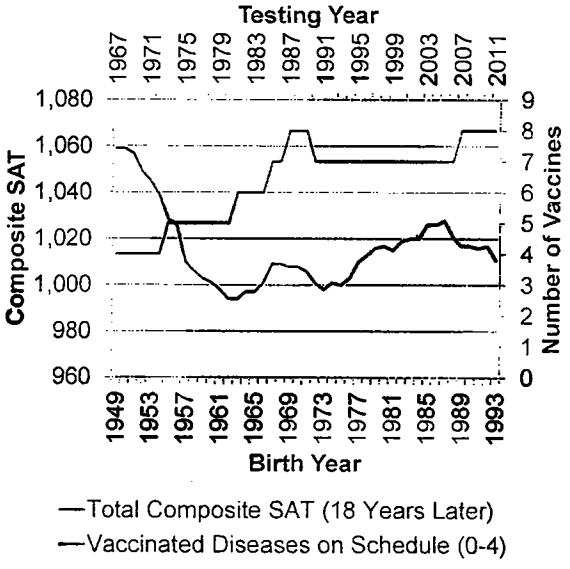
TDP Research

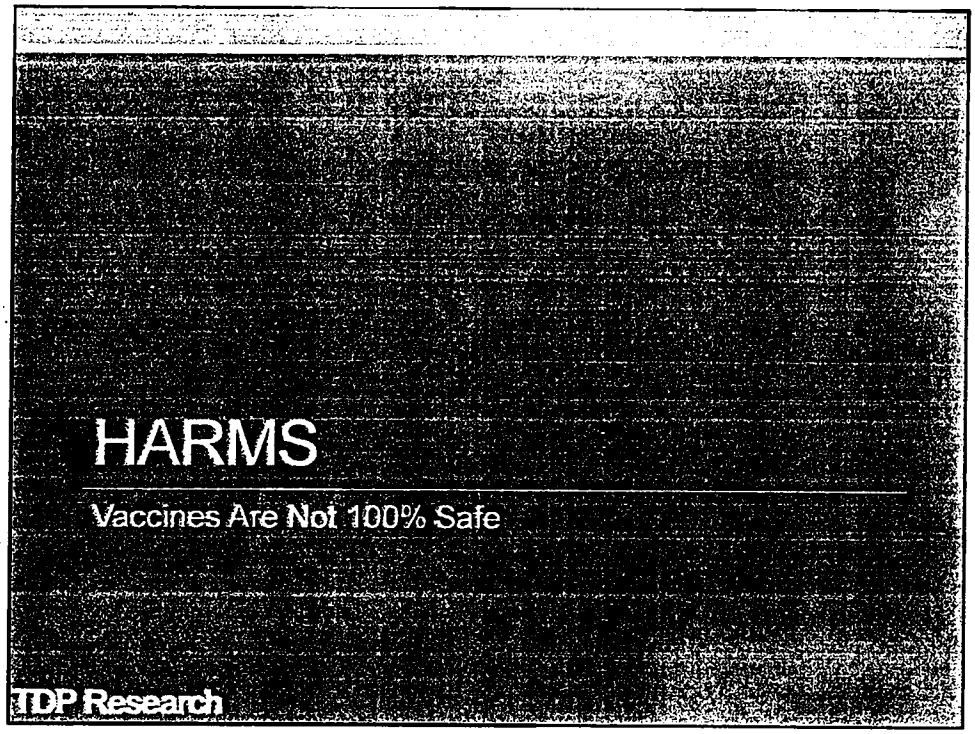
Vaccines and SAT Scores

College Board

United States Department of Education

Centers for Disease Control





Vaccine damage reported to VAERS in almost a full year

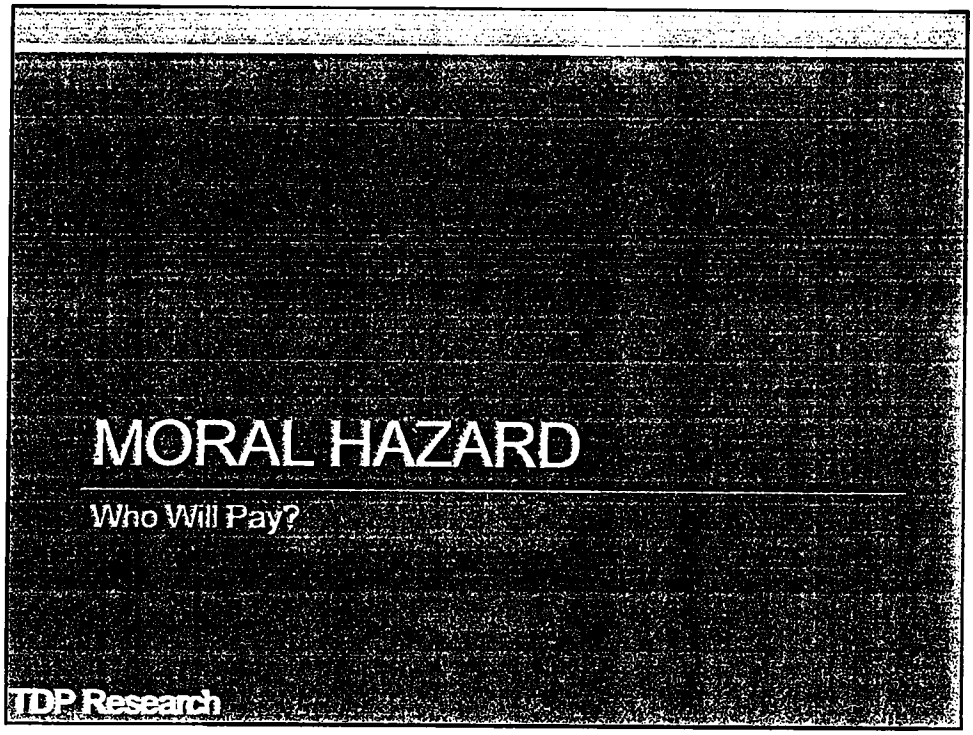
From the Department of Health and Human Services, Vaccine Adverse Effect Reporting System (For 2011 through, December 14, 2011)

11,250 reported injuries or deaths to children under the age of 18 reported in 2011.

- 23 of these incidences occurred in Vermont

99 vaccine related deaths of children reported in 2011

- Five year old child in Vermont was given the DTaP vaccine on February 7, 2011. On February 8, 2011, he was pronounced dead.



Vaccine Injury Compensation Trust Fund

Health Resources and Services Administration, 2012

- Funded by a $0.75 excise tax on vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. The excise tax is imposed on each dose (disease that is prevented) of a vaccine. Trivalent influenza vaccine for example, is taxed $0.75 because it prevents one disease; measles-mumps-rubella vaccine, which prevents three diseases, is taxed $2.25.
- The fund paid $234,789,690.24 for injuries and attorneys' fees in 2011.

Cannot Sue For Vaccine Injuries

Bruesewitz v. Wyeth (2011)

- "We hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects,"
- Justice Antonin Scalia in the majority (6-2) decision.

How Much Does a Vaccine Producer Make?

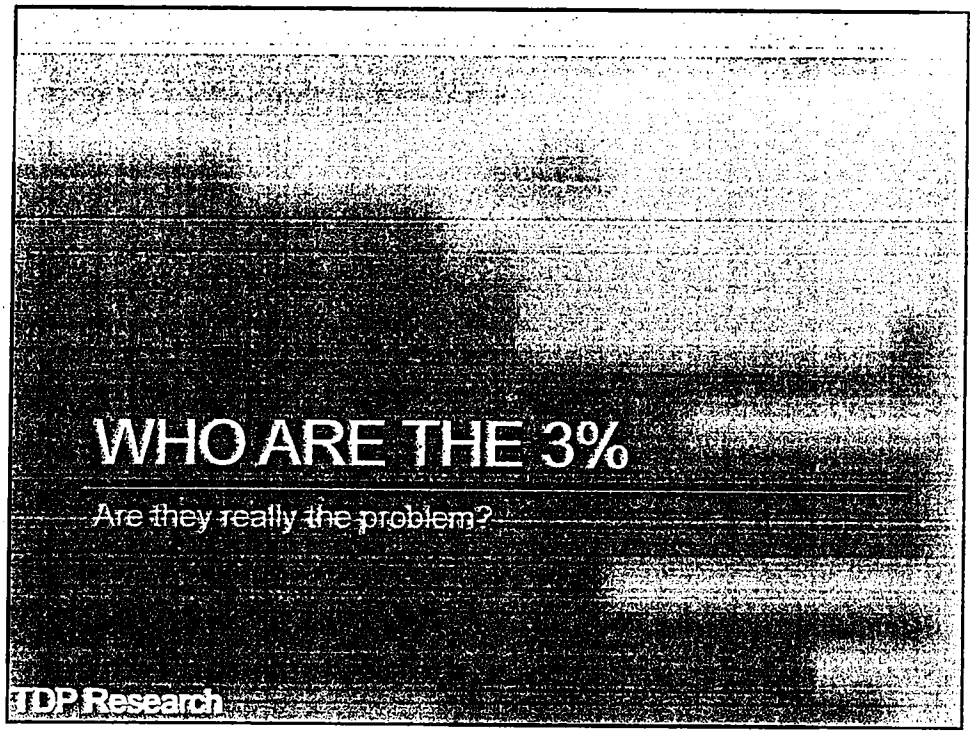
Merck 2011 10k statement filed with the SEC

- According to filings with the SEC, Merck sold almost $3.5 billion worth of vaccines in 2010.
  - $1.378 billion from ProQuad, MMR-II, and Varivax
  - $988 million from Gardasil
  - $519 million from RotaTeq
  - $376 million from Pneumovax
  - $243 million from Zostavax

Moral Hazard

The Economist

- A vaccine company, such as Merck, produces ~$3.5 billion in revenues from immunizations.
- If one of Merck's vaccines causes an injury, then Merck cannot be sued.
- This is a classic Moral Hazard. A company with insurance, may take greater risks than it would do without it because it knows it is protected.



Who are the 3%?

60% vaccination rate reported VHD

40% exemption rate reported by VHD

Of the 40%: 3% were reported as religious and philosophical.

> Than 3% of the total exemptions are philosophical

- Will forcing < 3% actually change the health of Vermonters?
- With a 60% vaccine rate Vermont was ranked the healthiest state.
- 37% of the unvaccinated are medical exemptions.
- Who are the < 3%?

The < 3% of the 40% who choose to exempt their children from vaccines

- Parents whom question the safety of DNA from human or animal source injected into their child.
- Parents who have experienced one or more side-effects in themselves or their children.
- After reviewing the pros & cons have decided one or more vaccine in not safe enough for their child.

Parents Have The Right To Choose

Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.. Washington, D.C.: U.S. Government Printing Office, 1949.

- The Nuremburg Code, in its outline for medical regulations and ethical guidelines, is clear:
- *The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.*

Parents need to maintain the right to make healthcare decisions for their own children

- When it comes down to it, it is the child who has the vaccine that assumes all the risks involved in participating in the vaccine program.
- The parents are the only ones who have the legal authority to speak for the child.

DR. JERRY LALIBERTE 2/3/12 S.199
KRISTEN CONNOLLY, MD 3

February 2, 2012
Senator Claire Ayer
Vermont State Senate
Senate Health and Welfare Committee
115 State Street
Montpelier, VT 05633

Dear Senator Ayer,

We write to you today as medical residents training in Pediatrics at Fletcher Allen/University of Vermont to urge you to pass S. 199 to remove the "philosophical exemption" from Vermont's vaccination laws. This issue is critically important to our patients and their families.

As the current law stands it is much easier for parents to opt their children out of required vaccines, such that Vermont now has among the lowest percentages of vaccinated children in the United States. This lower vaccine rate has serious implications for the herd immunity effect of vaccines to protect those of us who are fully vaccinated. As residents, we see children whose parents opt not to vaccinate and the consequences can be devastating. Not only are we seeing increased cases of pertussis across the country and Vermont, but other vaccine preventable diseases are slowing gaining traction in our local communities.

As pediatric residents we have organized a petition signed by full time and community pediatric faculty, nurses, residents, and medical students at Pediatric Grand Rounds on 2/2/2012 in support of S. 199 which will remove the philosophical exemption from Vermont's vaccination laws. My colleagues and I strongly urge you to pass this important piece of legislation. This law is essential to maintaining the health of our children in Vermont.

Sincerely yours,

John Cole, MD Kristen Mconnolly MD

John Cole, MD and Kristen Connolly, MD

SIGNATURES (Please sign name followed by degree) Vaccinations for Children – Proposal to Remove "Philosophical Exemption"		
NAME (print)	**Signature (degree)**	**Residence (town, state)**
Gerald Mirgon	MD	Burlington VT
Darrel Shumer	MD	Burlington VT
ANN GUILLOT MD		BURLINGTON, VT
Barb Kennedy M.D		Shelburne, VT
Kelly Cunningham		Burlington, VT
Andrew Washburn	MD	Shelburne, VT
Heather Bradley		Jericho VT
Frances Brennan		Lyndonville, VT
Jennifer Carlson	MD	Jericho, VT
William Gordon MD		CHARLOTTE, VT
Steve Hale	MD	Burlington, VT
William Danchy		Burlington, VT
Matthew Davies		Essex Junction, VT
Amelia Hopkins	MD	Burlington, VT
John Cole	MD	S. Burlington, VT
Molly Rideout		So. Hero, VT
Lauren Farley	MD	Burlington VT
SEAN KAVENAW	MD	" "
Beth Friesen	CPNP	Hinesburg VT
Lauren McLaughlin	MD	Burlington, VT
Kelli C. Lord		Burlington, VT
Rachel Cohen	MD	Burlington, VT
Jillian Sullivan		Stowe VT
Mari Berg		Charlotte, VT
Christa Zehle		Burlington, VT
Paul Rosenau	MD	Shelburne, VT
Tracey Wagner	RN	Swanton, VT
Nicole Guy	RN	ESSEX JCT, VT
Shannon Babbie	RN	Orwell, VT
Sarah Lane		Swanton, VT
Ashley Maynard-Tobin		Milton, VT

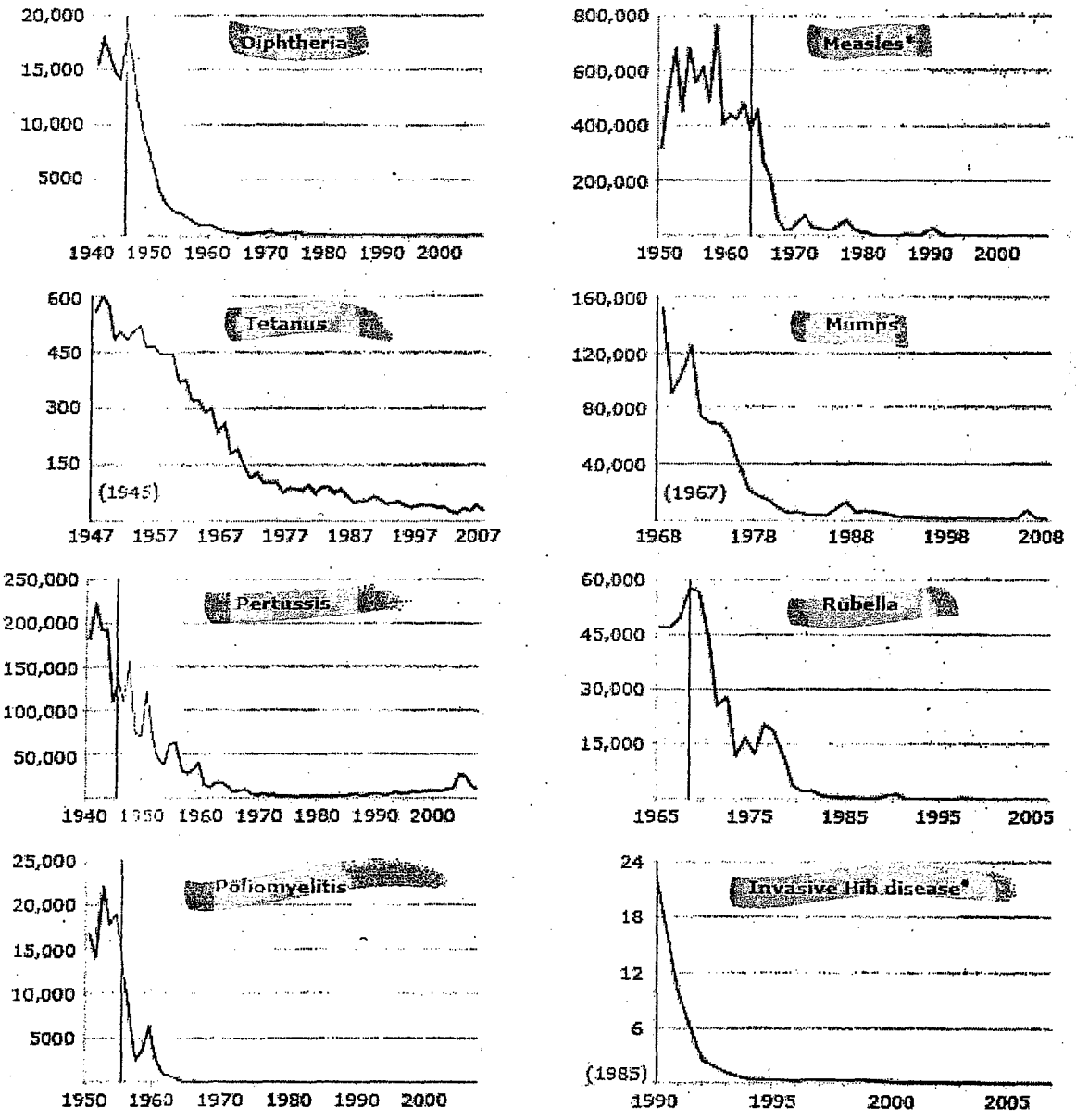
SIGNATURES (Please sign name followed by degree) Vaccinations for Children – Proposal to Remove "Philosophical Exemption"		
NAME (print)	**Signature (degree)**	**Residence (town, state)**
Ida McNamara	Ida McNamara RN	Burlington, VT
Ryan Good	MD	Burlington, VT
Tim Rogers	MD	Burlington, VT
Shannon Evans	MD	Burlington, VT
Emily Davie	Emily Davie MD	Essex Jct, VT
Ingrid Calle	D.O	Winooski, VT
Bryan Clark	MS III	Essex Junction, VT
Nancy Bricker	MD	Underhill, VT / Burlington VT
Paul Parker		Richmond VT
Catherine Naber		Burlington, VT
Denise Aronzon, MD	MD	South Burlington, VT
Lewis First		Burlington, VT.
Kristen Connolly, MD		South Burlington, VT
Monica Fiorenza, MD		Hinesburg VT
Chris Cahill	MS III	Burlington, VT
Sarah Hardy	MD	Burlington, VT
Katie Zlotek	RN	S. Burlington, VT
Lisa Emerson		Burlington VT
Beth Hayward		Jericho VT
Jill Nikkhah, MD		S. Burlington, VT
Gregory Connolly, MD		S. Burlington, VT
Katie DellAngelo		Burlington, VT
Karen Leonard	MD	Williston, VT
Karen Farnsworth		Hinesburg, Vt.
Kris Vroegop RNC		Burlington VT.
FRAN GRIMASON	MSN RN	Shelburne, Vt
Anne Pernicka		Jeffersonville, Vt.
Valerie Conte		Miltons, VT
F. Holly Sanazin		Colchester, VT
Patricia DeMarco		Charlotte, VT
Deana Chase		Swanton, VT

SIGNATURES (Please sign name followed by degree) Vaccinations for Children – Proposal to Remove "Philosophical Exemption"		
NAME (print)	**Signature (degree)**	**Residence (town, state)**
Monica Ploof	Monica M. Ploof CPNP	Burlington, VT
Marshall Lamb		So Burlington, VT
Rebecca Goodman	Rebecca Goodman MD	Winooski, VT
Jerry Larrabee		Burlington, VT
Stanley Weinberger	MD	Burlington, VT
Rebecca Collman McMahon	Rebecca Collman McMahon MD	Colchester VT
LOU DiNICOLA	MD	RANDOLPH, VT
Aaron Burley		Winooski, VT
DAVID STIFLER	MD	ESSEX, VT
Alan Hoffman	MD	HUNTINGTON, VT
H. Taylor Yates MD	H. Taylor Yates MD	Swanton, VT
Barbara Frankowski MD		Jericho VT
Laura Gould	Laura Gould, CCLS	South Burlington, VT
Catherine Rude MD	MD	South Hero, VT
NATASHA FIGUEIREDO, RN		ESSEX JUNCTION, VT
MARTINA KAEER	MD	SOUTH BURLINGTON, VT
Anne Morris	Anne Morris, MD	Burlington, VT

REP GEORGE TILL
2/3/12 S.199

GRAPHICS

Effectiveness of routine childhood immunizations



Vermont Recommended Child & Teen Vaccination Schedule 2011

	Vaccine	Birth	2 Months	4 Months	6 Months	12–15 Months	15–18 Months	Assure your child is up to date by age 2	Prior to Kindergarten: 4–6 Years	Prior to 7th Grade: 11–12 Years	13–18 Years
Required for child care / Required for school	*Haemophilus influenzae* type b (Hib)		Hib	Hib	Hib	Hib					
	Pneumococcal (PCV)		PCV	PCV	PCV	PCV					
	Hepatitis B (HepB)	HepB	HepB		HepB						
	Diphtheria, Tetanus, Pertussis (DTaP)		DTaP	DTaP	DTaP		DTaP		DTaP		
	Poliovirus (Polio) (IPV)		IPV	IPV	IPV				IPV		
	Measles, Mumps, Rubella (MMR)					MMR			MMR		
	Varicella (Chicken pox)*					Varicella			Varicella		
	Tetanus, Diphtheria, Pertussis (Tdap)									Tdap	
	Meningococcal (MCV4)**									MCV4	MCV4 second dose, after age 16
Recommended	Hepatitis A (HepA)					HepA	HepA				
	Rotavirus (RV)		RV	RV							
	Human Papillomavirus (HPV)									HPV 3 doses over 6 months	
	Influenza				Influenza	Every flu season					

6/2011

* Vaccine or documentation of history of disease.

** Recommended for all. Required only for residential students entering 7th grade and newly enrolled in 8-12.

Vermont's immunization schedule is compatible with the current recommendations of the Advisory Committee on Immunization Practice (ACIP) of the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

For more information, contact the Vermont Department of Health Immunzation Program:

Phor `02-863-7638 toll free (in VT): 800-640-4374 website: Hr `hVermont.gov

VERMONT
DEPARTMENT OF HEALTH

GEORGE TILL 2
2/3/12

7-1-2011

Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury

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ARTICLE

UNANSWERED QUESTIONS FROM THE VACCINE INJURY COMPENSATION PROGRAM: A Review of Compensated Cases of Vaccine-Induced Brain Injury

MARY HOLLAND, LOUIS CONTE, ROBERT KRAKOW AND LISA COLIN*

INTRODUCTION

Is the Vaccine Injury Compensation Program ("VICP") of the U.S. Court of Federal Claims a fair forum? This is not a trivial question as it is the only forum in which parents may bring claims for vaccine injury to their children. Under the 1986 National Childhood Vaccine Injury Act ("1986 Law"), Congress created an administrative forum that it meant to ensure simple justice for children; it gave the VICP original jurisdiction for all vaccine injury claims.[1] Because almost all U.S. children must

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* Mary Holland, Research Scholar and Director of the Graduate Legal Skills Program, NYU School of Law; Louis Conte, independent investigator; and Robert Krakow and Lisa Colin, attorneys in private practice. Pace Law School provided significant research support for this study. The authors thank former Environmental Law Dean Alexandra Dunn and law students Jillian Petrera, Kyle Caffrey, Sohad Jamal, Alison Kaplan, Georgine Bells, Jonne Ronquillo, Lisa Hatem, Allison Kazi and Adrienne Fortin. The authors also thank volunteers who worked under the direction of Louis Conte. For purposes of disclosure, Robert Krakow and Lisa Colin represent clients and have claims on behalf of family members in the Vaccine Injury Compensation Program.

1. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-11(2)(A) (2006). "All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program." H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344. After filing in the program, petitioners may reject program judgments or opt out of it to bring claims in state or federal court, but initial claims over $1,000 in damages must be made in the VICP. *Id.* at 12.

receive vaccinations to be able to attend daycare and school,[2] it is of utmost importance that this tribunal provides equitable treatment, transparency, and justice to those children who have the grave misfortune to be injured by the very vaccines intended to keep them healthy.

The VICP has had a mixed history in the eyes of the families of the vaccine-injured.[3] While some parents of vaccine-injured children supported the 1986 Law, over time many came to view it with "bitter disappointment."[4] Already by the mid-1990's, HHS had reduced the grounds for presumptive causation, and thus recovery, for vaccine injury in ways that many observers found troubling.[5] But the VICP's greatest challenge yet lay ahead.

That challenge began in 2002, when nearly five thousand families filed petitions with the VICP claiming that vaccines had caused their children's neurological disorder called "autism."[6] Starting in the late 1980's, the frequency of autism diagnoses

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2. *See State Requirements*, NATIONAL NETWORK FOR IMMUNIZATION, http://www.immunizationinfo.org/vaccines/state-requirements (last visited Feb. 28, 2011) (providing a searchable list of vaccine requirements for children by state).

3. *See, e.g.*, Brief for the National Vaccine Information Center, et al. as Amici Curiae Supporting Petitioners, Bruesewitz v. Wyeth, 130 S.Ct. 1734 (2010) (No. 09-152), *available at* http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_09_10_09_152_PetitionerAmCuNVICand24Orgs.authcheckdam.pdf.

4. *Id.* at 13 (quoting the testimony of Barbara Loe Fisher before Congress in 1999: "There is bitter disappointment and pervasive unhappiness among parents . . . with the current structure and administration of the vaccine injury compensation program . . . .").

5. HHS removed the presumption of recovery from "residual seizure disorder" in March, 1995, forcing families, like the Bruesewitz family in *Bruesewitz v. Wyeth*, to prove causation. *See* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7680 (Feb. 8, 1995) (codified as amended at 42 C.F.R. pt. 100); *see also* Andreu *ex rel.* Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009).

6. *See* Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *1 (Fed. Cl. Oct. 11, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Leroy%201.pdf.

began to skyrocket.[7] In an unprecedented proceeding, the VICP created and conducted the Omnibus Autism Proceeding, consolidated hearings meant to bring justice to these claims. The VICP dismissed all the "test case" claims of vaccine-induced autism, and the Court of Appeals for the Federal Circuit upheld all the decisions on review.[8]

Despite apparent judicial clarity and finality in these decisions, significant questions remain. Are the cases of "autism" that the VICP rejected in the Omnibus Autism Proceeding really different from the cases of "encephalopathy" and "residual seizure disorder" that the VICP has compensated before and since? Is it possible the VICP rejected cases of "autism" because of the hot-button label and not because of real differences in injuries or evidence?

This preliminary study suggests that the VICP has been compensating cases of vaccine-induced encephalopathy and residual seizure disorder associated with autism since the inception of the program. Through this preliminary study, the authors have found eighty-three cases of autism among those compensated for vaccine-induced brain damage.[9] This finding raises fundamental questions about the integrity, transparency, and fairness of this forum.

This assessment of compensated cases showing an association between vaccines and autism is not, and does not purport to be, science. In no way does it explain scientific causation or even necessarily undermine the reasoning of the decisions in the Omnibus Autism Proceeding based on the scientific theories and medical evidence before the VICP. Nor does this article have anything to say about state childhood immunization mandates in general.

What this article does point to are unanswered questions about vaccines and autism, a thorny issue that affects

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7. Michael E. McDonald & John F. Paul, *Timing of Increased Autistic Disorder Cumulative Incidence*, 44 ENVTL. SCI. & TECH. 2112, 2112 (2010), *available at* http://www.all.org/pdf/McDonaldPaul2010.pdf.

8. *See infra* notes 127-135.

9. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms.

approximately one in one hundred and ten children.[10] On this point, this study strongly suggests the need for further Congressional and scientific investigation to explore the association between vaccine-induced brain injury and autism and the integrity of this federally-administered compensation program.[11]

In Part I, we review the 1986 Law that created the VICP and the Omnibus, background information on autism, the Department of Health and Human Services' ("HHS") concession in the *Poling* case, and attempts to get information about autism from compensated cases of vaccine injury. Part II details the published cases in the VICP that note autism or autism-like symptoms and information about settled cases manifesting autism that parental caregivers have confirmed. It discusses the cases and includes representative questionnaire responses from parents and caregivers. Part III highlights unanswered questions, makes recommendations, and draws conclusions. Appendices include diagnostic information, definitions, excerpts from a Freedom of Information Request, a list of previously published articles evaluating compensated cases from the VICP, and a copy of the parent structured interview form.

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10. *See CDC Features, CDC Study: An Average of 1 in 110 Children Have an ASD,* CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/features/countingautism (last visited Jan. 18, 2010).

11. The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation. *See National Vaccine Injury Compensation Program, About VICP,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ (last visited Feb 28, 2011). HHS, DOJ, and the Court of Federal Claims jointly oversee the VICP. *Id.*

I. THE VACCINE INJURY COMPENSATION PROGRAM (VICP) AND THE OMNIBUS AUTISM PROCEEDING

1. The VICP and the 1986 National Childhood Vaccine Injury Act

Congress created the VICP as part of the 1986 National Childhood Vaccine Injury Act (1986 Law).[12] Congress passed this legislation to achieve several objectives: (1) to create the infrastructure for a national immunization program;[13] (2) to insulate industry and the medical profession from liability;[14] (3) to establish a program to compensate the injured;[15] and (4) to promote safer vaccines.[16]

The 1986 Law outlined an ambitious agenda for vaccine research, production, procurement, distribution, promotion, and purchase of vaccines.[17] It established the VICP to compensate "vaccine-related injury or death."[18] In its legislative history, Congress asserted that the purpose of the program was "to establish a federal no-fault program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity."[19] Congress enacted the statute to compensate children who had been injured while serving the public good.[20]

The program requires parents of vaccine-injured children to file first in the VICP before any other court.[21] The Court of Federal Claims in Washington, D.C. oversees the program.[22]

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12. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 34 (2006).
13. *Id.* § 300aa-2.
14. *Id.* § 300aa-11(a)(3).
15. *Id.* § 300aa-10(a).
16. *Id.* § 300aa-27(a).
17. *Id.* § 300aa-2.
18. 42 U.S.C. § 300aa-10(a).
19. H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.
20. *Id.*
21. 42 U.S.C. § 300aa-11.
22. *Id.* § 300aa-12.

After filing in the VICP, however, petitioners retain the right to go to civil court after waiting a specified period of time or rejecting a VICP decision.[23] Congress intended to create a largely administrative program as an alternative to the civil tort law system.[24] The purpose of the VICP was to establish a federal "no-fault" compensation program. The Congressional Committee Report noted that the "system is intended to be expeditious and fair" and to compensate recognized vaccine injuries "without requiring the difficult individual determinations of causation of injury."[25] The purpose of the statute was to overcome the inadequacies of the existing tort system for vaccine-injured children. "[F]or the relatively few who are injured by vaccines – through no fault of their own – the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. . . .Yet futures have been destroyed and mounting expenses must be met."[26]

When Congress passed the 1986 Law, there were several recognized vaccine injuries, including anaphylaxis, encephalopathy, paralytic polio, chronic arthritis, residual seizure disorder, and death.[27] All the injuries on the Vaccine Injury Table were to have occurred within thirty days of vaccination.[28] Most injuries listed in the Table described events that must occur within hours or three days of a child receiving a vaccine.[29] If petitioners met the exact requirements of the specified injuries, then they would not be required to litigate and would receive compensation through an administrative "no-fault" process.[30]

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23. *Id.* § 300aa-21.

24. H.R. REP. NO. 99-908, at 13 ("The Committee [on Energy and Commerce] anticipates that the speed of the compensation program, the low transactions costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.").

25. *Id.* at 12.

26. *Id.* at 6.

27. *See* P.L. 99-660, 100 Stat. 3743 (codified as amended at 42 U.S.C. § 300aa-14), *available at* http://www.hrsa.gov/vaccinecompensation/authorizinglegislation.pdf.

28. *Id.* Paralytic polio had a time period of 30 days; most injuries were to have occurred within 3 days. *Id.*

29. *Id.*

30. *Id.*

For injuries that were not listed on the Table, however, petitioners would have to prove these injuries based on a preponderance of the evidence, a "more likely than not" standard.[31]

The VICP insulates vaccine manufacturers from liability and requires that petitioners bring their petitions solely against HHS. They may not sue manufacturers or healthcare practitioners.[32] The rationale for this industry and professional protection was to ensure a stable childhood vaccine supply and to keep prices affordable.[33] The VICP awards compensation out of a Vaccine Injury Trust Fund collected from an excise tax of $0.75 imposed on the sale of every vaccine.[34]

Petitioners try their cases in the VICP before Special Masters of the Court of Federal Claims. Eight Special Masters act as the sole finders of fact and law.[35] The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.[36] Congress intended this informality to benefit the

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31. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-13(a)(1) (2006).

32. *Id.* § 300aa-11(a); *see also* H.R. REP. NO. 99-908, at 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353 ("[T]he bill requires that a person with an injury resulting from a vaccine that was administered after the enactment of this legislation file a compensation petition and go through the compensation program before proceeding with *any* litigation against a manufacturer." (emphasis added)).

33. *See, e.g.*, Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 408 (2004) ("Vaccine manufacturers quickly learned their lesson and threatened to halt production unless guaranteed indemnification by the federal government. As a result, vaccine shortages ensued, prices skyrocketed, and Congress was forced into action.").

34. *National Vaccine Injury Compensation Program, Vaccine Injury Compensation Trust Fund*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm (last visited Jan. 11, 2011) ("The Trust Fund is funded by a $0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine)."). In other words, a consumer would pay $2.25 as an excise tax on the MMR vaccine, or $0.75 on each of the measles, mumps and rubella antigens.

35. 42 U.S.C. § 300aa-11.

36. U.S. CT. FED. CLAIMS VACCINE R. 8(b)(1) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.").

petitioners by making the forum simpler and less costly.[37] Decisions of the Special Masters do not serve as precedent in subsequent proceedings in state or federal court.[38]

Petitioners may receive $250,000 in the event of a vaccine-related death and a maximum amount of $250,000 for pain and suffering.[39] These caps have not changed since 1986.[40] The 1986 Law also provides for "reasonable attorney's fees and costs" for bringing a petition, so that petitioners do not have to pay lawyers out of pocket or out of the proceeds of a judgment (as they would have to do in civil court under a contingency fee arrangement).[41]

The 1986 Law requires that petitions be filed "[no more than] 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury [after the administration of the vaccine]."[42] This three-year statute of limitations is shorter than many state tort statutes and does not provide for tolling when plaintiffs did not, or could not, discover the injury within the three-year statute of limitations.[43]

In perhaps the most significant part of the statute, the 1986 Law restricts vaccine manufacturers' and vaccine administrators' liability in any court unless petitioners file first in the VICP.[44]

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37. H.R. Rep. No. 99-908, at 3 (The purpose of the statute is "to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity.")

38. 42 U.S.C. § 300aa-12(4)(A), which provides that "information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." In other words, all records are sealed and do not become part of the court record in subsequent civil lawsuits.

39. *Id.* §§ 300aa-15(a)(2), (4).

40. *Id. Cf.* P.L. 99-660, 100 Stat. 3743 (codified as amended at 42 U.S.C. §§ 300aa-15(a)(2), (4)), *available at* http://www.hrsa.gov/vaccinecompensation/authorizinglegislation.pdf.

41. *See* 42 U.S.C. § 300aa-15(e)(1).

42. *Id.* § 300aa-16.

43. Cloer v. Sec'y of Health & Human Servs., 85 Fed. Cl. 141, 147 (Fed. Cl., 2008). A case on equitable tolling and discovery of injury in vaccine cases is currently before the Court of Appeals for the Federal Circuit for an *en banc* hearing to be heard in 2011. *See* Cloer v. Sec'y of Health & Human Servs., No. 2009-5052, 2010 WL 4269396 (Fed. Cir. Oct. 25, 2010).

44. *See* 42 U.S.C. § 300aa-22.

Starting in 1988, no vaccine manufacturer was liable for a vaccine-related injury or death from one of the recommended vaccines "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."[45] This language stems from the Second Restatement of Torts.[46] The U.S. Supreme Court decided *Bruesewitz v. Wyeth*, which dealt specifically with this provision in February 2011.[47]

In addition to broad liability protection, the 1986 Law also provides another shield to manufacturers under federal law.[48] The 1986 Law permits them the right to not disclose known risks to parents or guardians of those being vaccinated. Resting on the "learned intermediary" doctrine, manufacturers bear no liability for giving, or failing to give, accurate or complete information to those vaccinated, and have only to provide relevant information to doctors, who must give patients CDC Vaccine Information Statements.[49]

The Court of Appeals for the Federal Circuit has established a petitioner's burden of proof in a series of cases.[50] It requires that a petitioner prove:

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45. *Id.* § 300aa-22(b)(1).

46. Restatement (Second) of Torts § 402(A) cmt. k (1965).

47. In 2008, the Supreme Court of Georgia held that civil courts must decide on a case-by-case basis whether a vaccine-related injury is unavoidable for claims of vaccine design defect. Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236 (Ga. 2008). By contrast, in 2009, the Third Circuit Court of Appeals held that all vaccine injuries allegedly due to design defect are "unavoidable" under the 1986 Law because of federal preemption. Bruesewitz v. Wyeth, Inc., 561 F.3d 233, 242-46, 255-56 (3d Cir. 2009), *cert granted*, 130 S.Ct. 1734 (2010). On February 22, 2011, the Supreme Court affirmed the Third Circuit's ruling 6-2 that the 1986 Law preempts all civil vaccine design defect claims. Justice Scalia wrote the majority opinion; Justice Sotomayor wrote a dissent, strongly disagreeing with the majority's interpretation. Bruesewitz v. Wyeth, No. 09-152, 2011 WL 588789 (Feb. 22, 2011), *available* at http://www.supremecourt.gov/opinions/10pdf/09-152.pdf.

48. *See* 42 U.S.C. § 300aa-22(c).

49. *See id.*; CDC, *Vaccine Information Statements*, www.cdc.gov/vaccines/pub/vis/default.htm (last visited Mar. 21, 2011).

50. *See* Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also* Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); Andreu *ex rel.* Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374-75 (Fed. Cir. 2009).

(1) a medical theory causally connecting the vaccination and the injury;

(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and

(3) a showing of a proximate temporal relationship between vaccination and injury.[51]

The Court articulated the reason for this lower burden than that necessary in civil court "to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."[52] Petitioners are not required to show the precise mechanism of injury[53] but are "merely required to show that the vaccine in question caused their injury. . .."[54] This burden of proof applied in the Omnibus, as it does in all VICP cases.

2. The Vaccine-Autism Controversy

Vaccines have been controversial since Edward Jenner initiated their widespread use in England in the 1700s.[55] Some argue that the contemporary U.S. movement for vaccine safety and choice began with Lea Thompson's television special *DPT Roulette* in 1982.[56] That film depicts many individuals who suffered from the kinds of injuries that the VICP later compensated. The individuals that the film depicted had devastating disabilities – seizures, mental retardation, autism, paralysis, blindness, and deafness, among others. That film led directly to the creation of Dissatisfied Parents Together, which later became the National Vaccine Information Center ("NVIC"),

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51. *Althen*, 418 F.3d at 1278.

52. *Id.* at 1280.

53. *See* Knudsen *ex rel* Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

54. Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 100 (Fed. Cl. 2005).

55. For history of controversy about vaccines, see Robert Johnston, *Contemporary Anti-Vaccination Movements in Historical Perspective*, *in* THE POLITICS OF HEALING: HISTORIES OF TWENTIETH-CENTURY NORTH AMERICAN ALTERNATIVE MEDICINE 259, 259-86 (Robert Johnston ed., 2004).

56. *See DPT: Vaccine Roulette* (NBC television broadcast Apr. 19, 1982); *see also* PAUL OFFIT, DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL 2-7 (2010) [hereinafter DEADLY CHOICES].

the leading U.S. vaccine safety organization.[57] Throughout the late 1980's and early 1990's, NVIC publicly advocated for the right to informed consent for vaccination and highlighted the risks of vaccine injury. Harris Coulter and Barbara Loe Fisher's book, A SHOT IN THE DARK, about adverse reactions to the DPT vaccine, questioned the childhood immunization program's safety.[58]

The U.S. vaccine controversy grew in the late 1990's. In 1997, Congressman Frank Pallone of New Jersey attached an amendment to a Food and Drug Administration ("FDA") reauthorization bill, requiring the FDA to "compile a list of drugs and foods that contain intentionally introduced mercury compounds, and . . . provide a quantitative and qualitative analysis of the mercury compounds in the list."[59] The bill later evolved into the FDA Modernization Act of 1997 ("FDAMA") and was signed into law on November 21, 1997.[60]

In 1998 and 1999, U.S. vaccine manufacturers responded to FDA requests by providing detailed information about their mercury-containing vaccine preservative, thimerosal.[61] Thimerosal had been used as a preservative in vaccines since the 1930s because of its strong anti-bacterial properties.[62] The use of thimerosal allowed vaccine manufacturers to produce and distribute vaccines more cheaply by packaging and distributing them in multi-use vials.[63] Several of the vaccines on the routine

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57. NAT'L VACCINE INFO. CTR., http://www.nvic.org/ (last visited Jan. 20, 2011).

58. *See generally* HARRIS LIVERMORE COULTER & BARBARA LOE FISHER, DPT: A SHOT IN THE DARK (1985).

59. Mercury Environmental Risk and Comprehensive Utilization Reduction Initiative, H.R. 2910, 105th Cong. § 9(a) (1997).

60. Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 301 (2006); *see also* AM. ACAD. OF PEDIATRICS, HEPATITIS CONTROL REPORT (1998), *available at* http://www.aapsonline.org/vaccines/hcr.pdf.

61. *Vaccines, Blood & Biologics, Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm (last visited Feb 28, 2011).

62. *Id.*

63. *Id.*

childhood immunization schedule contained thimerosal, including the diphtheria-tetanus-pertussis combination vaccine.[64]

In 1999, the Public Health Service ("PHS") of HHS and the American Academy of Pediatrics ("AAP") issued a joint statement on thimerosal in vaccines. It stated:

> PHS and AAP continue to recommend that all children should be immunized against the diseases indicated in the recommended immunization schedule. Given that the risks of not vaccinating children far outweigh the unknown and much smaller risk, if any, of exposure to thimerosal-containing vaccines over the first 6 months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.[65]

After the joint statement, parents of autistic children inferred the possibility that mercury-containing vaccines might have contributed to their children's developmental regression through a unique form of mercury poisoning. In 2001, several authors published an article in MEDICAL HYPOTHESES, entitled *Autism: a novel form of mercury poisoning*, postulating that autism might be the result of mercury in vaccines.[66] Parents of children with autism began to file lawsuits around the country for compensation from vaccine-induced injury.[67] Since the late 1990's, the vaccine-autism debate has continued, with new

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64. In the 1990s, the DPT vaccines contained thimerosal. MMR notably does not contain thimerosal because it contains live viruses that the thimerosal might otherwise kill. For a list of childhood vaccines and their thimerosal content, see *id.* at Table 1.

65. Pub. Health Serv., U.S. Dep't. of Health & Human Servs., *Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, 48 MORBIDITY & MORTALITY WKLY. REP. 563 (1999), *available at* http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/mm4826a3.htm.

66. *See generally* S. Bernard et al., *Autism: a Novel Form of Mercury Poisoning*, 56 MED. HYPOTHESES 462 (2001), *available at* http://www.nationalautismassociation.org/library/anovelform.pdf.

67. *See generally* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459 (2008).

developments in medicine and science,[68] and with authors taking positions both for and against a possible vaccine-autism link.[69]

3. What is Autism?

"What is autism?" This deceptively simple question is at the heart of this problem. Today, "autistic disorder" is considered a psychiatric diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-IV"), the standard reference for the classification.[70] The diagnostic criteria, included in Appendix I in full, include (1) impairments in social interaction, (2) impairments in verbal and non-verbal communication, and (3) stereotypical restricted or repetitive patterns of behavior and interests.[71] There are no universally accepted biomarkers such as physical characteristics or blood or urine tests. The three domains of diagnostic criteria for autistic disorder cover a wide spectrum, from individuals with no language, almost no social interaction and severe behavioral problems, to extremely high-functioning individuals with intense interests and quirky personalities. The range of autistic disorders in the DSM-IV formally includes autism, Rett's Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, and Pervasive Development Disorder Not Otherwise Specified ("PDD-NOS").[72]

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68. For a review of scientific studies supporting a possible link between vaccines and autism, *see* Carol Stott & Andrew Wakefield, *An Urgent Call for More Research*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 49, 49 (Louise Kuo Habakus & Mary Holland eds., 2011). For scientific studies disconfirming a possible link between vaccines and autism, see *Vaccine Safety, Thimerosal*, CTRS. FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/vaccinesafety/Concerns/ thimerosal/index.html (last visited Jan. 18, 2011).

69. *See, e.g.*, SETH MNOOKIN, THE PANIC VIRUS: A TRUE STORY OF MEDICINE, SCIENCE, AND FEAR (2011); DEADLY CHOICES, *supra* note 56; PAUL A. OFFIT, AUTISM'S FALSE PROPHETS: BAD SCIENCE, RISKY MEDICINE, AND THE SEARCH FOR A CURE (2008); ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER (2007); DAVID KIRBY, EVIDENCE OF HARM: MERCURY IN VACCINES AND THE AUTISM EPIDEMIC: A MEDICAL CONTROVERSY (2005).

70. AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV-TR) § 299.00, 377-78 (4th ed. 2000).

71. *Id.* at 75.

72. *See id.* at 76-84.

Because autistic disorder is defined only by an aggregation of symptoms, there is no meaningful distinction between the terms "autism" and "autism-like symptoms." This article makes the distinction only to accurately reflect the terms that the Court of Federal Claims, caregivers, and others use. It is not a distinction to which the authors attach significance.

One of the most striking characteristics of autism is its dramatic rise since the early 1990's. For decades, the autism prevalence was approximately five cases per ten thousand children.[73] In December 2009, the Centers for Disease Control ("CDC") announced that the rate among eight-year olds was one case per one hundred and ten, or approximately 1% of all U.S. children.[74] Although for two decades, HHS and U.S. professional medical associations argued that rising rates of autism were attributable solely to better diagnoses, more inclusive categories, and diagnostic substitution, in 2009 the government acknowledged a real rise due at least in part to environmental factors. As Dr. Thomas Insel, Director of the National Institute of Mental Health and Chair of the Interagency Autism Coordinating Committee, said in light of the one in one hundred and ten numbers, "There is no question that there has got to be an environmental component here."[75] A recent study by scientists at the Environmental Protection Agency identified autism's "changepoint year" as 1988-89, pinpointing the start of a dramatic rise in prevalence.[76]

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73. Catherine Rice, *Prevalence of Autism Spectrum Disorders - Autism and Developmental Disabilities Monitoring Network, United States, 2006*, 58 MORBIDITY & MORTALITY WKLY. REP. 1 (2009), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5810a1.htm ("Before the 1980s, the term 'autism' was used primarily to refer to autistic disorder and was thought to be rare, affecting approximately one in every 2,000 (0.5%) children," i.e. 5 per 10,000.).

74. *See CDC Features, CDC Study: An Average of 1 in 110 Children Have an ASD,* CTRS. FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/features/countingautism (last visited Jan. 18, 2010).

75. David Kirby, *Rising Autism Numbers -- Leading Federal Official Says "No Question" That Environmental Exposures Are A Factor*, HUFFINGTON POST (Dec. 21, 2009), *available at* http://www.huffingtonpost.com/david-kirby/rising-autism-numbers_b_397978.html. (Article is accompanied by transcript).

76. Michael E. McDonald & John F. Paul, *Timing of Increased Autistic Disorder Cumulative Incidence*, 44 ENVTL. SCI. & TECH. 2112, 2112 (2010), *available at* http://www.all.org/pdf/McDonaldPaul2010.pdf; *see also* Irva Hertz-

Although there have been isolated historical accounts of individuals with autistic qualities, particularly with 'genius' or 'savant' qualities, the modern phenomenon was first described by child psychiatrist Leo Kanner in 1943.[77] Kanner first noted many of the characteristics that form the core of the syndrome: impaired language, social skills, and repetitive behaviors. But his careful case series analysis failed to ascribe significance to certain related symptoms, including unusual feeding patterns and gastrointestinal problems in the children, and he failed to look at possible environmental exposures that might have been causal.

In *The Age of Autism: Mercury, Medicine and a Manmade Epidemic*, a historical account of autism's rise, Dan Olmsted and Mark Blaxill traced the actual identities of most of the original children in Kanner's 1943 case series.[78] All of the identified children in the case series had experienced known or plausible exposures to ethyl mercury, a then newly-created synthetic chemical.[79] Ethyl mercury was used at that time in both vaccines and as an agricultural fungicide; the children in the case series had parents either in the medical profession working on vaccines or parents in agriculture using fungicides.[80] While the mercury connection to autism is not proven, there are many sources, including the Olmsted-Blaxill book,[81] that give the hypothesis plausibility.[82]

Picciotto & Lora Delwiche, *The Rise in Autism and the Role of Age at Diagnosis*, 20 EPIDEMIOLOGY 84 (2009).

77. *See* Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 NERVOUS CHILD 217 (1943), *available at* http://affect.media.mit.edu/Rgrads/Articles/pdfs/Kanner-1943-OrigPaper.pdf.

78. *See* DAN OLMSTED & MARK BLAXILL, THE AGE OF AUTISM: MERCURY, MEDICINE, AND A MAN-MADE EPIDEMIC (2010).

79. *Id.* at 1-16, 347-64.

80. *See id.* at 163-365.

81. *See id.*

82. Other recent studies that note correlations between mercury, other environmental toxins and autism include Mary Catherine DeSoto & Robert T. Hitlan, *Sorting Out the Spinning of Autism: Heavy Metals and the Question of Incidence*, 70 ACTA NEUROBIOLOGIAE EXPERIMENTALIS 165 (2010); Mary Catherine DeSoto, *Ockham's Razor and Autism: The Case for Developmental Neurotoxins Contributing to a Disease of Neurodevelopment*, 30 NEUROTOXICOLOGY 331 (2009); Raymond F. Palmer et al., *Proximity to Point Sources of Environmental Mercury Release As a Predictor of Autism Prevalence*,

One must note that the DSM-IV definition of "autistic disorder" is similar on its face to the VICP's definitions of "encephalopathy, seizures and sequela."[83] The VICP's description of acute encephalopathy for children eighteen months of age and older, including "significant change in mental status" and "significantly decreased level of consciousness," is consistent with the DSM-IV's criteria for onset before age three of "autistic disorder." The dimensions of autistic disorder are consonant with the VICP's detailed description of "decreased level of consciousness":

> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
>
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).[84]

In other words, lack of normal eye gaze, impaired social relations, and non-responsiveness to external stimuli are noted in both the DSM-IV autism and VICP encephalopathy classifications as diagnostic criteria. To be sure, the DSM-IV classification differs from the VICP description, but DSM-IV "autistic disorder" does not contradict the VICP description of encephalopathy, seizures, and sequela. Indeed, scientific

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15 HEALTH & PLACE 18 (2009). It is interesting that Kanner himself noted that a biological etiology of autism might have been overlooked. In the foreword to BERNARD RIMLAND, INFANTILE AUSTIM: SYNDROME AND ITS IMPLICATIONS FOR A NEURAL THEORY OF BEHAVIOR (1964), Kanner wrote:

The concept of 'early infantile autism' (I could not think of a better name) was diluted by some to deprive it of its specificity, so that the term was used as a pseudo-diagnostic wastebasket for a variety of unrelated conditions, and a nothing-but psychodynamic etiology was decreed by some as the only valid explanation, so that further curiosity was stifled or even scorned.

Id. at v.

83. *See infra* Appendices I and II.

84. *Compare infra* Appendix I *with infra* Appendix II.

literature acknowledges that the conditions often coexist.[85] These descriptions, when put side by side, show significant similarities.

4. The Omnibus Autism Proceeding

Families alleging vaccine-induced autism filed lawsuits against vaccine manufacturers in state and federal courts around the country starting in 1999. In 2002, the Court of Federal Claims *Leroy v. HHS* decision largely ended such litigation.[86] Finding that the mercury-containing preservative was "vaccine-related" under the 1986 Law, the Chief Special Master ruled that all thimerosal cases were required to be consolidated and filed first in the VICP, as all other vaccine-related injuries. Potential petitioners viewed thimerosal as a preservative, and not as truly vaccine-related. Furthermore, they wanted to litigate in regular civil courts, where they would enjoy rights to discovery, potentially high compensatory and punitive damages, and juries. None of those dimensions are available in the VICP.

Nonetheless, five thousand petitioners filed claims in the VICP of vaccine-induced autism on thimerosal and MMR causation theories. The VICP decided it would hold hearings on these two test theories with three "test cases" for each theory, to decide "general causation," that would apply to all cases with similar claims, and "specific causation," for the individual children's claims. Many thousands more cases were barred from filing because the strict three-year statute of limitations had expired. In addition, some petitioners filed in the VICP and then moved their cases to state and federal courts after the required waiting period to bring lawsuits against vaccine manufacturers on the theory of vaccine design defect.[87]

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85. *See, e.g.*, S.E. Bryson et al., *Prevalence of Autism Among Adolescents with Intellectual Disabilities*, 53 CAN. J. PSYCHIATRY 449, 449 (2008); R. Tuchman & I. Rapin, *Epilepsy in Autism*, 1 LANCET NEUROLOGY 352, 353 (2002).

86. *See* Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680 (Fed. Cl. Oct. 11, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Leroy%201.pdf.

87. *See, e.g.*, Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236, 236-38 (Ga. 2008).

On February 12, 2009, Special Masters of the Federal Court of Claims released long-awaited decisions in the first Omnibus Autism Proceeding test cases. The Special Masters ruled that (1) there was no plausible link between the MMR vaccine and autism, and that (2) the three "test case" petitioners for this causation theory—Michelle Cedillo, Colten Snyder, and Yates Hazlehurst—deserved no compensation. The Special Masters did not simply conclude that the science disfavored petitioners. They issued scathing opinions that rejected and demeaned petitioners' scientific theories, expert witnesses and treating physicians.

Special Master Hastings proclaimed that the Cedillo case was "one-sided," that the doctors who advised Michelle Cedillo were "*very wrong*," (emphasis in original).[88] He wrote that the physicians who found a link between Michelle's severe maladies and her vaccines "misled" the Cedillos and "are guilty. . .of gross medical misjudgment."[89] Special Master Vowell, in the Snyder case, similarly characterized the petitioners as "victims of bad science," and suggested that "an objective observer would have to emulate Lewis Carroll's White Queen and be able to believe six impossible (or, at least, highly improbable) things before breakfast" to decide in petitioners' favor.[90] In short, the Special Masters decided that (1) there was no reliable science supporting an MMR-thimerosal-autism link, (2) the petitioners' physicians were "guilty of gross medical misjudgment," and (3) the parents who pursued unproven vaccine injury treatments were "misled by physicians."[91]

The next year, in 2010, the same Special Masters released their decisions in the William Mead, Jordan King, and Colin Dwyer test cases on the second theory of mercury-induced

88. Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at *134 (Fed. Cl. Feb. 12, 2009), *available at* http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Hastings-Cedillo.pdf.

89. *Id.* at *135.

90. Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at *198 (Fed. Cl. Feb. 12, 2009), *available at* http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/Vowell.Snyder.pdf.

91. *See Cedillo*, 2009 WL 331968, at *135.

autism, again finding no basis for compensation.[92] These three test case petitioners elected not to appeal their decisions. Among those arguing MMR-induced autism in the first set of test cases, both Cedillo and Hazlehurst lost on appeal[93] and Snyder did not appeal.[94]

The Court of Appeals for the Federal Circuit did not affirm automatically the *Cedillo* and *Hazlehurst* decisions. In the *Hazlehurst v. HHS* oral argument, the judges wanted to know what would happen if later science confirms the thimerosal-autism theory?[95] What will happen to the children's claims? The judge answered his own question, saying that Congress could add thimerosal-induced autism to the Table of Injuries and state that those who had previously been denied compensation would still be eligible.[96] The appellate court judges seemed not to find the vaccine-autism theory as implausible as had the Special Masters.

Similarly, the panel of appellate judges in *Cedillo v. HHS* asked the Department of Justice ("DOJ") tough questions.[97] Two of the three judges were clearly troubled that DOJ had introduced an expert report to rebut key petitioner biological evidence without introducing the underlying lab results or books, something that all parties agreed would have been impossible

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92. *See* Mead v. Sec'y of Health & Human Servs., No. 03-215V, 2010 WL 3584449 (Fed. Cl. Aug. 20, 2010); King v. Sec'y of Health & Human Servs., No. 03-584V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); Dwyer v. Sec'y of Health & Human Servs., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010). All three cases are available online. *See Autism Decisions and Background Information,* U.S. FED. COURT OF CLAIMS, http://www.uscfc.uscourts.gov/node/5026 (last visited Mar. 1, 2011).

93. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1349-50 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/cedillo.fedcir.pdf; Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343, 1354 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Hazlehurst_Affirmance.pdf.

94. *See Snyder*, 2009 WL 332044, at *198.

95. Transcript of Oral Argument, Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2009-5128/all.

96. *Id.*

97. Transcript of Oral argument, Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2010/all/cedillo.html.

under the Federal Rules of Civil Procedure.[98] They probed whether DOJ had asked for the lab books (they hadn't)[99] or how DOJ could be sure that the expert report was reliable when DOJ didn't have the underlying data (when the DOJ lawyer assured the judge that the data would have reinforced the expert's conclusions, the judge laughed, as did observers in the courtroom).[100] The judges were similarly troubled that DOJ failed to notify petitioners that they were seeking the expert report in the first place, as surely DOJ should have been well aware that surprise was an entirely inappropriate tactic in the VICP, which Congress meant to be petitioner-friendly and non-adversarial.[101] While the appellate judges in both *Hazlehurst* and *Cedillo* decided in favor of HHS and against petitioners, they did so after contentious oral argument, and the judges noted in *Cedillo v. HHS* that DOJ's conduct troubled them.[102]

After the final Omnibus appeals were decided in the summer of 2010, by all appearances, the vaccine-autism case in the VICP was closed. The Court of Federal Claims sent out letters to all petitioners telling them, in so many words, that unless they could allege different theories and provide compelling experts and evidence, their cases would be dismissed without hearing on the basis of the Omnibus general causation test cases.[103]

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98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1342 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/cedillo.fedcir.pdf; Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343, 1354 (Fed. Cir. 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Hazlehurst_Affirmance.pdf ("We agree with petitioners that the government's failure to produce or even to request the documentation underlying Dr. Bustin's reports is troubling, but we think that in the circumstances of this case, that failure does not justify reversal.").

103. *See* Autism Update-September 29, 2010, *In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2002 WL 31696785 (Fed. Cl. July 3, 2002), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/autism%20update%209%2029%2010.pdf; COURT OF FED. CLAIMS, GUIDANCE TO PETITIONERS ON HOW TO EXIT THE VACCINE PROGRAM 1 (2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/EXITING_GUIDANCE_TO_PRO_SES.pdf.

5. The Poling Concession

During the preparation for the second set of test cases in the Omnibus that would consider whether thimerosal-containing vaccines cause autism, a major, unanticipated event occurred: HHS conceded one of the slated test cases. In a report required by Court Rule 4(c), leaked to the press, HHS conceded that vaccines, including the MMR, had triggered Hannah Poling's encephalopathy and subsequent developmental regression.[104] HHS's description of the child's condition implied a distinction between "autism-like symptoms" and "autism," although there was no ambiguity that Hannah Poling in fact had autism.[105] The concession document "concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations CHILD received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder."[106] This concession led to some interest in the press on the vaccine-autism link and the role of mitochondrial conditions.[107] In 2010, the Poling financial compensation decision was published and showed that HHS paid over $1.5

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104. *See* David Kirby, *The Vaccine-Autism Court Document Every American Should Read,* HUFFINGTON POST (Feb. 26, 2008), *available at* http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-d_b_88558.html; *see also* U.S. CT. FED. CLAIMS VACCINE R. 4(c), *available at* http://www.uscfc.uscourts.gov/sites/default/files/court_info/Vaccinerules_20100111_v4.pdf.

105. Jon S. Poling et al, *Developmental Regression and Mitochondrial Dysfunction in a Child With Autism*, 21 J. OF CHILD NEUROLOGY 170, 171 (2006).

106. *See* Kirby, *supra* note 104. A brief excerpt from this concession report is also available at Poling v. Sec'y of Health & Human Servs., No. 02-1466V, 2008 WL 1883059 (Fed. Cl. Apr. 10, 2008). It is notable that this initial concession report merely mentions the MMR vaccine as 3 of 9 antigens administered to Hannah Poling in one office visit, whereas the final compensation decision, noted below in the Published Case Chart as Case 21, specifies MMR as the principal cause of her injury.

107. *See* Ginger Taylor, *The Role of Government and Media, in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 150, 156-57 (Louise Kuo Habakus & Mary Holland eds., 2011).

million in damages.[108] The relevant VICP website notes carefully, however, that while one case received compensation from the Omnibus, "HHS has never concluded in any case that autism was caused by vaccination."[109]

The Poling concession left unclear just how Hannah Poling might differ from the other five thousand claims of vaccine-induced autism in the Omnibus. Indeed, what made the matter particularly acute was that HHS and DOJ relied on the very same medical expert, making the very same medical diagnosis, to both compensate the *Poling* case and to dismiss one of the test cases, without that expert ever being cross-examined or testifying in person in the Omnibus about this apparent contradiction.[110] In late 2010, *The Economist* noted that far from settling the matter of mitochondrial dysfunction and a possible vaccine-autism link, the HHS concession left the matter unresolved.[111] The *Poling* concession raised key questions about the VICP's transparency and equitable treatment of petitioners. Just how different was Hannah Poling's case?

6. Attempts to Gain Information About Autism in Compensated Cases

After the Poling concession, journalists began looking for possible evidence of other cases of autism among VICP-compensated cases. Robert F. Kennedy, Jr. and David Kirby reported on the case of Bailey Banks, a boy whom the VICP

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108. Child Doe/77 v. Sec'y of Health & Human Servs., 2010 WL 3395654 at *4 (Fed. Cl. July 21, 2010), *available at* http://www.uscfc.uscourts.gov/sites/default/files/CAMPBELLSMITH.%20DOE77082710.pdf.

109. *National Vaccine Injury Compensation Program, Statistics Report, February 8, 2011*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ statistics_report.htm (last visited Mar. 3, 2011). The compensation decision for the Poling case, included below at Case 21, is based on "an MMR vaccine Table presumptive injury of encephalopathy." *Child Doe/77*, 2010 WL 3395654, at *1.

110. *See* Mary Holland & Robert Krakow, *The Right to Legal Redress, in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 39, 42 (Louise Kuo Habakus & Mary Holland eds., 2011).

111. *Energy Drain: The Case of Autism May be Faulty Mitochondria*, ECONOMIST (Dec. 1, 2010), *available at* http://www.economist.com/node/17626677.

compensated for vaccine-induced acute demyelinating encephalomyelitis ("ADEM"), leading to Pervasive Development Disorder Not Otherwise Specified, an autistic disorder.[112] Kirby also published a response he received from HHS about autism as a feature of VICP-compensated cases. He entitled it "Communication from Human Resources and Services Administration of HHS that it Does not Track Autism." In it, HHS wrote:

> From: Bowman, David (HRSA) [mailto:DBowman@hrsa.gov]
> Sent: Friday, February 20, 2009 5:22 PM
> To: 'dkirby@nyc.rr.com'
> Subject: HRSA Statement
>
> David,
>
> In response to your most recent inquiry, HRSA has the following statement:
>
> The government has never compensated, nor has it ever been ordered to compensate, any case based on a determination that autism was actually caused by vaccines. We have compensated cases in which children exhibited an encephalopathy, or general brain disease. Encephalopathy may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures.
>
> *Some children who have been compensated for vaccine injuries may have shown signs of autism before the decision to compensate, or may ultimately end up with autism or autistic symptoms, but we do not track cases on this basis.*
>
> Regards,

---

112. *See generally* Robert F. Kennedy, Jr. & David Kirby, *Vaccine Court: Autism Debate Continues*, HUFFINGTON POST (Feb. 24, 2009), *available at* http://www.huffingtonpost.com/robert-f-kennedy-jr-and-david-kirby/vaccine-court-autism-deba_b_169673.html; Banks v. Sec'y of Health & Human Servs., No. 02-0738V, 2007 U.S. Claims LEXIS 254 (Fed. Cl. July 29, 2007), *available at* http://www.uscfc.uscourts.gov/sites/default/files/ Abell.BANKS.02-0738V.pdf; *see also infra* Published Case Chart.

David Bowman
Office of Communications
Health Resources and Services Administration
301-443-3376[113]

The authors, perplexed by HHS's apparent disinterest in an association of vaccine injury with autism, decided to probe the issue further. Co-author Robert Krakow addressed a Freedom of Information Act ("FOIA") request to HHS asking whether it would be possible to obtain information[114] and documents regarding compensated vaccine injury claims. After receiving a response that such an undertaking would take four to five years and would cost approximately $750,000, the authors turned to Pace University School of Law to assist in their inquiry.

II. FURTHER INVESTIGATION

1. Compensated Cases of Vaccine Injury

The authors began a research project with Pace Law School students to locate and analyze VICP cases assessing whether the VICP had in fact compensated vaccine-induced brain damage, including autism, while perhaps not using that term specifically. Peer-reviewed medical and legal journals and prominent vaccine researchers have acknowledged the value of evaluating compensated claims in the past.[115] While recognizing that the legal standard of causation is not the same as scientific causation (also called "causality"), several authors have published articles on vaccine injury based on review of compensated claims for pertussis, polio, measles, rubella, and MMR vaccine injuries. The

113. *See* Ginger Taylor, *Vaccines Don't CAUSE Autism, They Just RESULT in Autism,* ADVENTURES IN AUTISM BLOG (Sept. 9, 2010, 4:13 PM), http://adventuresinautism.blogspot.com/2010/09/vaccines-dont-cause-autism-they-just.html (emphasis added). For an excerpt of the email, see also Kennedy & Kirby, *supra* note 112.

114. *See infra* Appendix III.

115. *See infra* Appendix IV, which highlights the governmental and scholarly use of the VICP-compensated cases as a source of valuable information on vaccine injury.

authors have included scientists at the CDC, the Institute of Medicine, and the VICP.

a. VICP Published Cases Compensating Encephalopathy and Residual Seizure Disorder, Noting or Suggesting Autism or Autism-like Symptoms

The authors, with the assistance of Pace Law students, created a database of VICP published decisions that used relevant terms related to autism. Through this search of final VICP decisions or case stipulations, we found twenty-one decisions that acknowledged autism or autism-like symptoms associated with vaccine-induced encephalopathy and seizure disorder. The following table summarizes the cases and stipulations with language that strongly suggests autistic features:

Published Case Chart

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
1	Alger v. Sec'y of Health & Human Servs.	1990 WL 293408, at *4 (Cl. Ct. July 13, 1990).	His mental development has been arrested. . . .He doesn't speak and will never communicate verbally. He doesn't respond to verbal communication. He is not toilet trained. . . .He is self-destructive and very difficult to manage. He needs constant one-on-one care to protect him from injuring himself and others."
2	Sorensen v. Sec'y of Health & Human Servs.	1990 WL 290491, at *1 (Cl. Ct. Dec. 6, 1990).	"Petitioners further maintain that the injuries resulted in permanent disabilities involving significant developmental delay, moderate autistic characteristics, and mental retardation."
3	Kleinert v. Sec'y of Health & Human Servs.	1991 WL 30664, at *2, *4 (Cl. Ct. Feb. 20, 1991).	"Today he has a seizure disorder which is under control and a condition known as over-focusing, similar in some respects to autism. . . . As a sequela to the encephalopathy, Wes Ian Kleinert suffered complications for more than six months after the administration of the DPT vaccine, and he continues to suffer from these complications, which have developed into a residual seizure disorder and autistic tendencies."
4	Connor v. Sec'y of Health & Human Servs.	1991 WL 133618, at *6 (Cl. Ct. July 3, 1991).	"[R]espondent's report. . .suggests vaguely. . .that Kenny's problems 'can be attributed in part to other causes such as a family history of epilepsy, autism and tonsillar hypotrophy. . .Dr. Spiro did not even purport to know what *did* cause Kenny's seizure disorder; his basic point was that in his view the DTP did *not* cause it."

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
5	Messner v. Sec'y of Health & Human Servs.	1991 WL 74145, at *4 (Cl. Ct. Apr. 22, 1991).	"Jennifer is a severely mentally retarded individual with hyperactive and destructive behaviors. . . .Her social functioning is extremely inappropriate: she is belligerent and sometimes aggressive;. . .she. . .practices self stimulating behavior; and she repeatedly bites her hand. . . .She presents a danger to herself and to family members."
6	Oxley v. Sec'y of Health & Human Servs.	1991 U.S. Cl. Ct. LEXIS 575, at *4.	"Richelle's disabilities include autistic-like behavior, hyperactivity, and partially controlled seizures. Richelle is totally dependent on others for her care and needs constant supervision and assistance. . . .She is non-verbal but signs several words."
7	Underwood v. Sec'y of Health & Human Servs.	1991 WL 156659, at *1 (Cl. Ct. July 31, 1991).	"In addition, respondent noted that Travis' medical records indicate that he suffered from mental retardation and autism. These conditions, according to respondent, are not related to the residual seizure disorder."
8	Sharpnack v. Sec'y of Health & Human Servs.	1992 WL 167255, at *8 (Cl. Ct. June 29, 1992).	"The evidence shows that Megan exhibits some very difficult behavioral problems that interfere with her education and social adjustment. Her behavior, which includes head banging, pulling her own hair, and scratching at things, must be constantly redirected. Her disruptive and noncompliant behavior has become a major barrier to progress in functioning."

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
9	Koston v. Sec'y of Health & Human Servs.	974 F.2d 157, 158-59 (Fed. Cir. 1992).	"[A]pproximately twelve hours after receiving her second DPT vaccination, Jenna experienced a seizure. . .Dr. Doris Trauner. . .concluded that Jenna suffers from a variant of Rett Syndrome. . . .[T]he Secretary wanted to assert that Jenna's seizures were caused by Rett Syndrome and not by the DPT vaccination."
10	Sanford v. Sec'y of Health & Human Servs.	1993 WL 177003, at *2 (Fed. Cl. May 10, 1993).	"Her condition is complicated by a behavior disorder. She is highly impulsive, has no concept of danger, cannot accept control, and has autistic tendencies."
11	Bastian v. Sec'y of Health & Human Servs.	1994 U.S. Claims LEXIS 196, at *16-17 (Fed. Cl. Sept. 22, 1994).	"Dr. Quinn opined that Kyle suffers from pervasive developmental disorder (PDD). . . .Dr. Quinn explained that PDD is caused by a brain insult. . . .Dr. Quinn indicated Kyle's post-vaccinal encephalopathy was the brain insult which in turn resulted in his PDD. Dr. Quinn opined, to a reasonable degree of medical certainty, that Kyle's condition is permanent."
12	Lassiter v. Sec'y of Health & Human Servs.	1996 U.S. Claims LEXIS 216, at *12 (Fed. Cl. Dec. 17, 1996).	"Respondent argues that Eric's current behavioral manifestations and retardation 'fit the pattern of autistic spectrum disorders with severe mental retardation.' Dr. Spiro summarizes: 'This child had a [DPT-related febrile] reaction following his DPT booster, but, it is clear that he currently fits into the autistic spectrum disorder with retardation. This group of disorders is totally unrelated to DPT, it usually constitutes a group of genetically determined or idiopathic disorders (without a clear known etiology.)'"

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
13	Suel v. Sec'y of Health & Human Servs.	1997 WL 617034, at *1, *3 (Fed. Cl. Sept. 22, 1997).	"Petitioners alleged that David suffered significant aggravation of his pre-existing tuberous sclerosis (TS) in the form of an encephalopathy and a residual seizure disorder. . . .Having seizures early in life is likely to lead to mental underdevelopment or mental retardation. Autism is a frequent occurrence among TS patients. Dr. Gomez has never seen an autistic TS child who did not have seizures."
14	Reitz v. Sec'y of Health & Human Servs.	1998 WL 228421, at *1, *4, *5 (Fed. Cl. Apr. 21, 1998).	"He would bang his head approximately six times and then return to normal. These episodes. . .[occur] almost daily. . . .Derrick has the cognitive skills of a two or three year old, and improves slowly. Although he speaks, he cannot do so in complete sentences. He has behavioral problems due to frustration. He receives behavioral therapy, occupational therapy, physical therapy, and speech therapy. He was never the same baby after the third DPT vaccination. . . .He lost milestones and development."
15	Tebcherani v. Sec'y of Health & Human Servs.	55 Fed. Cl. 460, 468 (2003).	"Dr. MacDonald [respondent's expert] noted that Lena carries a diagnosis of pervasive developmental disorder, also known as autistic spectrum disorder. In Dr. MacDonald's opinion, Lena's autism is not related to the DaPT vaccination . . . ."
16	Freeman v. Sec'y of Health & Human Servs.	2003 U.S. Claims LEXIS 285, at *26, n. 7 (Fed. Cl. Sept. 25, 2003).	"It was noted at the hearing that Kienan's neurologic disorder has features that might cause it to be labeled as 'atypical autism,' a condition within the category of 'autistic spectrum disorder.' I note, however, that even assuming that Kienan's disorder is correctly classified within the 'atypical autism' category, that is essentially irrelevant to my ruling concerning the entitlement issue in this case. As Dr.

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
			Kinsbourne explained, Kienan's autistic-type features seem to be a result of the brain damage that caused his severe mental retardation. As Dr. Kinsbourne further explained, brain damage is one of the many possible causes of autism. Thus, I cannot see why the fact that Kienan's disorder may fall within the autism spectrum has any substantial relevance to the question of what caused Kienan's seizure disorder and mental retardation."
17	Gancz v. Sec'y of Health & Human Servs.	2003, No. 91-0178V, 1 (Stipulation).	"Petitioners allege that Sarah sustained the first symptom or manifestation of the onset of seizures within the period set forth in the Table. They further allege Sarah developed autism and behavioral problems as the sequelae of her Table injury."
18	Noel v. Sec'y of Health & Human Servs.	2004 WL 3049764, at *13 (Fed. Cl. Dec. 14, 2004).	"Dr. Shafrir testified that Rachel had a reaction to her acellular DPT, which consisted of lethargy, irritability, and a high-pitched cry. He stated that her seizure disorder was independent of her DPT reaction, and that the seizure disorder led to epilepsy, developmental delay, and autism. She died of sudden unexpected death in epilepsy."
19	Paulmino v. Sec'y of Health & Human Servs.	69 Fed.Cl. 1, 4 (2005).	"Erika was described as: A four-year old female with intractable epilepsy, PDD [pervasive developmental disorder] . . . .As of the filing of this action, Erika continues to suffer from a developmental and speech-and-language disorder and requires therapy."

	Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
20	Banks v. Sec'y of Health & Human Servs.	2007 U.S. Claims LEXIS 254, at *54 (Fed. Cl. July 20, 2007).	"Bailey's ADEM [acute disseminated encephalomyelitis] was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD. Additionally, this chain of causation was not too remote, but was rather a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay."
21	Child Doe/77 v. Sec'y of Health & Human Servs.	2010 WL 3395654, at *1 (Fed.Cl. July 21, 2010).	"Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doe/77's pre-existing mitochondrial disorder based on an MMR vaccine Table presumptive injury of encephalopathy, which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela."

Seventeen of the twenty-one cases noted above mention the word "autism," "autistic," or one of the autistic disorders, Rett's Disorder or Pervasive Developmental Disorder.[116] Four cases describe developmental regression and self-injurious behaviors highly consistent with descriptions of severe autism.[117] Some of the cases rule that a vaccine caused brain injury, including autism. For instance, in the *Banks v. HHS* case, the Special Master wrote that the brain damage led "inexorably from vaccination to Pervasive Developmental Delay."[118] *Child Doe/77 v. HHS* concedes that vaccines aggravated a pre-existing mitochondrial disorder "which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder."[119]

Other cases deny that the autism in the child is in any way related to the vaccines or compensated brain injuries. For instance, in *Underwood v. HHS*, the government's position was that the child's mental retardation and autism "are not related to the residual seizure disorder."[120] Similarly, in *Koston v. HHS*, the government asserted that the "seizures were caused by Rett Syndrome and not by the DPT vaccination."[121] Whether or not vaccines "caused" or "resulted in" autism is not decided in all cases, although it is in some. What is clear, however, is that autism is sometimes associated with compensated vaccine-induced brain injury.

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116. The four cases above not using a specific autism-related term are Case 1, Alger v. Sec'y of Health & Human Servs., No. 89-31V, 1990 WL 293407 (Cl. Ct. July 13, 1990); Case 5, Messner v. Sec'y of Health & Human Servs., No. 90-552V, 1991 WL 74145 (Cl. Ct. Apr. 22, 1991); Case 8, Sharpnack v. Sec'y of Health & Human Servs., No. 90-983V, 1992 WL 167255 (Cl. Ct. June 29, 1992); Case 14 Reitz v. Sec'y of Health & Human Servs., No. 90-1344V, 1998 WL 228421 (Fed. Cl. Apr. 21, 1998).

117. *See* Case 1, *Alger*, 1990 WL 293407, at *4; Case 5, *Messner*, 1991 WL 74145, at *4; and Case 8, *Sharpnack*, 1992 WL 167255 at *8; and, Case 14, *Reitz*, 1998 WL 228421, at *1, *4, *5.

118. Case 19, Banks v. Sec'y of Health & Human Servs., No. 02-0738V, 2007 U.S. Claims LEXIS 254, at *54 (Fed. Cl. July 29, 2007).

119. Case 20, Child Doe/77 v. Sec'y of Health & Human Servs., 2010 WL 3395654, at *1 (Fed. Cl. July 21, 2010).

120. Case 7, Underwood v. Sec'y of Health & Human Servs., No. 90-719V, 1991 WL 156659, at *1 (Cl. Ct. July 31, 1991).

121. Case 9, Koston v. Sec'y of Health & Human Servs., 974 F.2d 157, 159 (Fed. Cir. 1992).

b. Settled Cases Suggesting Autism

The authors then decided to explore settled cases, like the *Poling* concession, to see if there might be more compensation decisions of vaccine-induced brain injury that included autism. Using the Federal Public Access to Court Electronic Records ("PACER") database of federal court dockets, the authors examined docket reports filed with the VICP that HHS had compensated without hearing.[122] The authors identified compensated cases of brain injury that they believed might include autism diagnoses. Then they used telephone and internet databases to identify telephone numbers and addresses for the compensated families. Under the direction of co-author Louis Conte, trained volunteers contacted compensated families and conducted telephone interviews using the questionnaire in Appendix V about the injured child and the family's experience in the VICP. The volunteers received instruction on making calls and, in particular, were instructed never to lead parents in their answers. If a parent said that a child did not have autism or autism-like symptoms, the volunteer accepted that description with no further questions. Based on these telephone conversations, the volunteers reached over sixty families of individuals compensated for encephalopathy or residual seizure disorder, or both, who concomitantly have or had autism or autism-like symptoms.

While these families' names and docket numbers are in the public domain, and that is how the authors retrieved information about them, the authors seek not to subject these families to unnecessary invasion of their privacy. They have all suffered extreme hardship in coping with their children's injuries, or in some cases, deaths, and we seek to shield them from unwanted attention. The authors are confident that both HHS and DOJ can easily confirm the accuracy of these compensated families, amounts, and vaccine injury codes. The only information the government agencies may not be able to confirm are the parental

122. *Pacer*, PUB. ACCESS TO COURT ELEC. RECORDS, http://www.pacer.gov (last visited Mar. 3, 2011).

reports of autism, but they can easily do this through direct contact if they seek to verify this information.[123]

2. The Social Communication Questionnaire

Recognizing that some readers might be skeptical of parental reports of autism without further substantiation, the authors had twenty-two compensated families complete a written, well-recognized autism screening questionnaire. This questionnaire in no way "proves" that these individuals have an autism diagnosis. The completed questionnaires do, however, give further credibility to the parental reports of autism. Only complete medically supervised diagnoses could fully confirm autism diagnoses. Such diagnoses were beyond the scope of this study, but the authors hope that future inquiry will include full evaluation of compensated individuals and their medical complications.

The Social Communication Questionnaire ("SCQ") is a forty-item parental report screening measure that "taps the symptomology associated with the autism spectrum disorder."[124] The questionnaire, drafted by Drs. Rutter, Bailey, and Lord, contains forty yes/no questions selected to have "discriminative diagnostic validity."[125] This simple instrument is meant to correlate to the complete ninety three-item Autism Diagnostic Interview-Revised ("ADI-R"), also written by Rutter and Lord, who are internationally renowned autism experts.[126] (These scientists filed expert reports in the Omnibus on behalf of HHS, rejecting the theory of a vaccine-autism link.)[127] The SCQ

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123. *See* Letter from Thomas Flavin, Freedom of Info. Officer, Dep't of Health & Human Servs., to Robert Krakow (July 9, 2009) (on file with authors); *see infra* Appendix III.

124. M. RUTTER ET AL., SCQ: THE SOCIAL COMMUNICATION QUESTIONNAIRE MANUAL 1 (2003).

125. *Id.*

126. *Id.*

127. *See* MICHAEL RUTTER, THIMEROSAL VACCINE LITIGATION (2008), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Expert%20Reports/King_03-584V/ExGG_Rutter_Report_03-584.pdf; *see also* CATHERINE LORD, THIMEROSAL VACCINE LITIGATION (2008), *available at* http://www.uscfc.uscourts.gov/sites/default/files/autism/Expert%20Reports/King_03-584V/Ex_W_Lord_Report_03-584.pdf.584.pdf.

focuses on behaviors that are "rare in nonaffected individuals."[128] The authors warn that while the screening questionnaire "is not suitable for individual diagnosis," the SCQ questions are based on the ADI-R, which is in turn used as the primary diagnostic instrument for the International Classification of Diseases-10 (World Health Organization, 1992) and the DSM-IV (American Psychiatric Association, 1994) diagnosis of autism. "These provide an operational diagnosis that is based on the behavioral item scores in three areas of functioning: Reciprocal Social Interaction; Communication; and Restricted, Repetitive, and Stereotyped Patterns of Behavior."[129]

The questionnaire recommends a cutoff score of fifteen or greater as an indication of a possible autism spectrum disorder. It notes that, "the mean score for children with autism was 24.2, which is well above the cutoff."[130] Rutter, Bailey, and Lord further clarify:

> [T]he agreement between the SCQ and the ADI-R at both the Total Score and domain score levels is high, with agreements being substantially unaffected by age, gender, language level, and performance IQ. The findings validate the SCQ as a screening questionnaire and show that it provides a reasonable index of symptom severity.[131]

Typically, caregivers received the SCQ questionnaires by email and returned the completed, scanned questionnaires by return email. While it was not possible to administer the SCQ to all the families, the volunteers did administer it to twenty-two parents or caregivers, representing 27% of the total number of cases.[132] All SCQ scores were at or above the cutoff point of fifteen, with most substantially above it.[133] The mean score of the twenty-two SCQ values is 24.4, or slightly higher than the

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128. RUTTER ET AL., *supra* note 124, at 1.

129. *Id.* at 9.

130. *Id.* at 3.

131. *Id.* at 22.

132. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms, including 22 SCQ scores, representing 27% of the total of 83 cases reported.

133. *Id.*

mean score of 24.2 that Rutter, Bailey, and Lord describe.[134] When caregivers reported that children were relatively high functioning, their children's scores were in fact closer to the cutoff point, suggesting the accurate nature of the screening device and of parental reports.[135] All SCQ scores on the table below fell between fifteen and thirty three, with both ends of this spectrum in the "autistic disorder" range.[136]

3. Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms

134. M. RUTTER ET AL., *supra* note 124, at 3.

135. Inference based on case histories on file with authors and validated by Rutter et al.'s findings that the SCQ "provides a reasonable index of symptom severity." *Id.* at 22.

136. *See infra* Table of VICP-Compensated Claims of Brain Injury That Include Autism or Autism-like Symptoms (for SCQ scores).

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
1	1989-1	DPT	UNAV	EN & RSD	B, D, F	25	$2,300,000	
2	1989-2	DPT	UNAV	EN & RSD	A		$1,400,000	
3	1990-1	DPT	UNAV	EN & RSD	A		Unknown	
4	1990-2	DPT	UNAV	EN & RSD	A		$1,700,000	
5	1990-3	DPT	UNAV	EN & RSD	A		$1,700,000	deceased, 25
6	1990-4	DPT	UNAV	RSD	D,F	30	$1,000,000	
7	1990-5	DPT	UNAV	EN & RSD	B, D, F	24	Unknown	
8	1990-6	DPT	UNAV	EN & RSD	B, F		$500,000	
9	1990-7	DPT	UNAV	EN & RSD	A		$2,000,000	
10	1990-8	DPT	UNAV	EN & RSD	A		$1,900,000	
11	1990-9	DPT	404	EN & RSD	F		$700,000	
12	1990-10	DPT	404	EN & RSD	D, F	25	$470,000	
13	1990-11	DPT	UNAV	EN & RSD	C, E, F		$2,100,000	
14	1990-12	DPT	404	RSD	E, F		$360,000	deceased, 23
15	1990-13	DPT	404	RSD	D, E	26	$917,000	
16	1990-14	DPT	400	RSD	B, F		$2,000,000	
17	1990-15	MMR	460	RSD	F		$465,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
18	1990-16	DPT	404	EN & RSD	A		$ 1,400,000	
19	1990-17	MMR	408	EN & RSD	B, E, F		$500,000	
20	1990-18	DPT	404	EN & RSD	D, F	18	$1,700,000	
21	1990-19	DPT	404	RSD	F		$1,000,000	
22	1990-20	DPT	406	RSD	F		$80,000	
23	1990-21	DPT	400	RSD	F		$778,000	
24	1990-22	DPT	404	EN & RSD	B,D,F	33	$1,900,000	
25	1990-23	DPT	404	RSD	F		$1,300,000	
26	1990-24	DPT	404	EN & RSD	D,F	24	$990,000	
27	1990-25	DPT	400	RSD	F		$2,600,000	
28	1990-26	DPT	404	EN & RSD	D, E, F	18	$1,200,000	
29	1990-27	DPT	404	EN&RSD	F		$919,000	
30	1990-28	DPT	404	RSD	F		$920,000	
31	1990-29	DPT	404	RSD	F		$1,200,000	
32	1990-30	DPT	404	RSD	C, D, F	22	$3,300,000	
33	1990-31	DPT	404	RSD	F		$630,000	
34	1990-32	DPT	404	EN & RSD	A		$2,400,000	
35	1990-33	MMR	408	RSD	F		$956,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
36	1990-34	MMR	408	RSD	F		$375,000	
37	1990-35	DPT	406	RSD	F		$519,000	deceased, 31
38	1990-36	DPT	404	RSD	D, F	23	$2,300,000	deceased, 15
39	1990-37	DPT	404	EN & RSD	D, F	21	$2,300,000	
40	1990-38	DPT	404	EN & RSD	A		$1,300,000	
41	1990-39	DPT	404	RSD	F		$747,000	
42	1900-40	DPT	404	EN & RSD	F		$1,700,000	
43	1990-41	DPT	404	EN & RSD	F		$2,500,000	
44	1990-42	DPT	404	RSD	F		$2,500,000	
45	1991-1	DPT	404	EN & RSD	D, F	27	$1,600,000	
46	1991-2	DPT	404	EN& RSD	F		$1,300,000	
47	1991-3	DPT	404	RSD	F, S		$4,400,000	
48	1992-1	DPT	458	EN & RSD	F		$820,000	deceased, 12
49	1992-2	DPT	404	RSD	F		$1,400,000	
50	1992-3	DPT	404	RSD	F		$1,300,000	
51	1992-4	DPT	458	RSD	F		$1,800,000	
52	1992-5	DPT	458	RSD	F		$535,000	
53	1993-1	DPT	458	RSD	C,D, F	15	$590,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
54	1993-2	DPT	400	RSD	F		$2,200,000	
55	1993-3	DPT	456	EN & RSD	F		$980,000	deceased, 21 (lightning)
56	1994-1	DPT	458	RSD	F		$1,700,000	
57	1995-1	DPT	404	RSD	D, F	23	$500,000	
58	1995-2	DPT	458	RSD	C, D, E, F	33	$2,000,000	
59	1995-3	DPT	458	RSD	D, F	20	$1,100,000	
60	1995-4	DPT	458	RSD	F		$1,100,000	
61	1995-5	DPT	456	RSD	F		$2,300,000	
62	1996-1	MMR	460	RSD	F		$3,100,000	
63	1997-1	DPT	458	RSD	D, F	21	$4,000,000	
64	1997-2	MMR	460	RSD	C, D, F	26	Unknown	
65	1997-3	DPT	456	RSD	E, F		$3,900,000	
66	1997-4	DPT	458	RSD	D, F	28	$985,000	
67	1998-1	DPT	458	EN & RSD	A, F		$600,000	
68	1998-2	DPT	458	EN & RSD	B, E, F		$1,100,000	
69	1998-3	DPT	458	EN & RSD	A		Pending	
70	1998-4	DPT	400	EN & RSD	A		$2,100,000	

#	Case by Year	Vaccine	Vaccine Injury Code	Injury Compensated	Documentation	SCQ Score	Compensation Amount	Deceased, Age
71	1999-1	DpaT & HiB	472	EN & RSD	A		$250,000	deceased, 5
72	1999-2	MMR	460	RSD	C, F		$335,000	
73	2000-1	MMR	460	RSD	E, F		$602,000	
74	2001-1	MMR	460	EN & RSD	A		$5,900,000	
75	2002-1	MMR	460	EN & RSD	E, F		$4,000,000	
76	2002-2	MMR	460	EN & RSD	A		$800,000	
77	2002-3	MMR	460	EN & RSD	A, D, E, F	31	$2,500,000	
78	2003-1	Thim.	492	EN	B, C		Pending	
79	2003-2	DpaT	458	EN & RSD	A, F		$1,600,000	
80	2003-3	DpaT	458	EN & RSD	A, E, F		Pending	deceased, 4
81	2006-1	MMR	460	EN & RSD	B, F		Pending	
82	2009-1	MMR	460	EN	E, F		Pending	
83	2010-1	DpaT	458	EN	D, F	23	$1,300,000	

Key to Chart:
UNAV – unavailable

Vaccines
DPT – diphtheria-pertussis-tetanus
DpaT – diphtheria – acellular pertussis - tetanus
MMR – measles-mumps-rubella
Thim. – thimerosal, an ethyl mercury containing preservative used in vaccines

Vaccine Injury Codes – from Court of Federal Claims "Nature-of-Suit Codes for Vaccine Cases"
400 – no longer on chart
404 – no longer on chart
406 – no longer on chart
408 – no longer on chart
456 – injury – DPT & polio
458 – injury – DTP/DPT
460 – injury – M/M/R
469 - other
472 – death – DTP/DPT

Injury Compensated and Symptoms Described
EN – Encephalopathy
RSD – Residual Seizure Disorder

Documentation Codes
A - Decision of Court of Federal Claims stating petitioner has autism or autism-like symptoms
B – Decision of Court of Federal Claims detailing symptoms and behavior consistent with autism
C – Third party medical, educational, or court records confirming autistic disorder on file with authors
D – Completed Social Communication Questionnaire by caregiver on file with authors (SCQ)

E – Previous public documentation by parents or caregivers in written, electronic or film media stating that the subject has autism or autism-like symptoms
F – Telephone interview with parent or caregiver in which the interviewee states that the subject has autism or autism-like symptoms
S – Stipulation in docket using term "autism" or "autism-like symptoms"

4. Interpretation

This discussion must start with the caveat that we are able only to interpret the subgroup of eighty-three compensated cases that we have located. Out of a total number of approximately two thousand five hundred compensated vaccine injury claims,[137] we recognize that this is a small subset.[138] It is our hope that this preliminary study will lead to more complete study of all cases of compensated vaccine injury. Such a study might provide a far more comprehensive understanding of vaccine injury.

Despite its limitations, this study suggests that compensated cases of vaccine-induced encephalopathy associated with autism started from the inception of the VICP in 1989 and have continued at least through 2010. Of these eighty-three compensated cases including autism, seventeen note an autistic disorder in a published decision of the Court of Federal Claims and twenty-two have SCQ questionnaires confirming caregiver reports of autism. In other words, thirty-nine of the eighty-three cases, or 47% of this sample, have confirmation of autism beyond parental report alone. The evidence of an association in these

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137. *National Vaccine Injury Compensation Program, Claims Filed and Compensated or Dismissed by Vaccine, October 12, 2010,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited Mar. 3, 2011).

138. While beyond the scope of this preliminary study, it is worth noting that in addition to these claims for compensation from vaccine injury, many parents and doctors have filed reports of autism as a vaccine injury in the federally-funded Vaccine Adverse Event Reporting System (VAERS). These reports of autism as an adverse vaccine event can be retrieved at www.medalerts.org by inputting "autism" as a symptom. There are 83 reports of autism as an adverse event that were filed between July 1, 1990 and June 30, 1999.

cases between recognized vaccine injuries (encephalopathy and residual seizure disorder) and autism exists.

It is notable that over a twenty-year period the VICP did not publicly acknowledge an apparent vaccine-encephalopathy-autism link. While in the early years of the program there might have been no particular attention to this association, certainly by the late 1990's, the question of vaccine injury and autism was one of general public interest. The finding of so many cases of autism among compensated cases calls into question HHS's assertions on the topic.

Several of the damage awards that HHS compensated included expenses uniquely related to autism. For example, such expenses included Applied Behavior Analysis ("ABA"), a form of educational intervention created and used for individuals on the autism spectrum.[139] In other cases, VICP-appointed life planners recommended that families install a fence as the child would be likely to wander later in life. Wandering is a well-recognized characteristic and danger for children with autism.[140]

In addition to the corroboration from the SCQs, the authors have newspaper, magazine, and blog articles on file, discussing the children's autistic symptoms and challenges. The authors also received medical and educational records confirming the children's autism diagnoses for some of the compensated individuals.

All of the cases of vaccine-induced encephalopathy associated with autism noted in the Table of VICP-Compensated Claims above were the result of combination vaccines – MMR, DTP or DTaP. The 1998 Weibel, et al. study of VICP-compensated cases of acute encephalopathy associated with the measles vaccine, alone or in combination, identified no cases of encephalopathy after administration of monovalent mumps and rubella vaccines

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139. *Mental Health, A Report of the Surgeon General, Other Mental Disorders in Children and Adolescents, Autism*, SURGEON GEN., http://www.surgeongeneral.gov/library/mentalhealth/chapter3/sec6.html#autism (last visited Mar. 3, 2011) ("Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior.").

140. *See e.g.*, AUTISM & WANDERING, NAT'L AUTISM ASS'N (2010), *available at* http://www.nationalautismassociation.org/pdf/autism_wandering_FULL%20SHEET%20BROCHURE.pdf.

and fewer cases of encephalopathy after administration of monovalent measles vaccines than of combination vaccines.[141] Geoffrey Evans, M.D., Director of the Division of Vaccine Injury Compensation of Health Resources and Services Administration ("HRSA"), was a co-author of the study.[142]

About half of the eighty-three reviewed cases have encephalopathy, residual seizure disorder, and autism. The other half of the reviewed cases have residual seizure disorder and autism. There is no obvious distinction in symptoms or gravity of injury among these cases. In addition, eight of the compensated children, or 10% of the group we identified, died before age thirty one. Seven of the eight died from seizures; one died from lightning. A shorter lifespan is associated with seizure disorder.[143]

5. Caregiver Responses

We include a few representative responses from families about their children and experiences in the VICP that families provided in telephone interviews. It bears remembering that these are the families who "won" in the VICP. On balance, it is logical to imagine that the "winning" families' views are at least

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141. Robert E. Weibel et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 PEDIATRICS 383, 383 (1998) ("No cases were identified after the administration of monovalent mumps or rubella vaccine.") In 48 cases of acute encephalopathy after measles vaccine, alone or in combination, 8 children received monovalent measles vaccines; 40 received multiple vaccines, including rubella, mumps, diphtheria, tetanus, pertussis, oral polio, and *Haemophilus influenza* Type B, together with measles vaccine. *Id.* at 384 -85.

142. Dr. Evan's position is noted at *National Vaccine Injury Compensation Program, Advisory Commission on Childhood Vaccines (ACCV) Roster,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/roster.htm (last visited Jan. 19, 2011).

143. *Seizures and Epilepsy: Hope Through Research*, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, NAT'L INSTS. OF HEALTH, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm (last visited Mar. 3, 2011) ("People with severe seizures that resist treatment have, on average, a shorter life expectancy and an increased risk of cognitive impairment, particularly if the seizures developed in early childhood.").

somewhat more favorable than the views of families who received no financial compensation.

Here are a few representative answers from families who participated in telephone interviews:

Question: How is your child's life today?

(A) A. is profoundly autistic. She is non-verbal, has major behavioral issues, is self-injurious. . .classic and very severe autism. . ..She cannot be left alone ever. . ..A. was a beautiful baby, who was developing normally, but who had obvious reactions to her first two DPT vaccines. One left her leg swollen and red, and she developed a high fever and screamed after the other. But the doctors did not hesitate to give A. her third DPT shot when she was 5 months old, and she went over the edge. She had the shot at 4:00 p.m., and by 6:00 p.m. she had a fever of 105 to 106 degrees. . ..After that day, she was gone. Over the years, we have lost many friends and are distant from many family members because A. is so hard to love and be around. It is very heartbreaking to see people reject her, and to have them suggest that we should have institutionalized her.[144]

(B) B. (aged 44) has no speech, no functional use of his hands, and will no longer stand. . ..He has a couple of seizures every day. . ..B.'s teeth had to be pulled because he would not allow anyone near his mouth to brush them. He is not potty trained. He is very sensory defensive, flaps his hands, and makes moaning noises.[145]

(C) C. is a "giant baby" because although she is an overweight 18-year-old, she functions at the level of a 2-year old. She has no life really, compared to her peers. She has very little functional communication, and can only say a few words, like "eat" or short phrases that she repeats incessantly. . ..She is still in diapers, with no probability that she will ever be potty trained. . ..C. now

144. Telephone Interview with M.M. and C.M., Parents of Vaccine Claimant (Sept. 30, 2010) (on file with authors as Case 13).

145. Telephone Interview with E.L. and L.L., Parents of Vaccine Claimant (July 22, 2010) (on file with authors as Case 30).

has frequent periods (every 4 to 6 months) of frustration, extreme rage, and self-injurious behavior.[146]

Question: What was the impact of the vaccine injury on your family?

Devastating.[147]

Question: Was your child's claim resolved fairly?

(A) No, it was a war.[148]

(B) DOJ attorneys were disrespectful and combative. . ..The Compensation Program should be about compensation and not about defense of the vaccine program.[149]

(C) The attorney for the government was absolutely horrible. She was cold, insulting, and did whatever she could to keep us from being compensated. She pushed for C. to be put in a group home because it would be cheaper than allowing her to live with her family, and she argued against very basic home safety devices, like latches on cupboards, a fence for the yard, and a special swing where C. would not fall out when a seizure hit.[150]

Question: What would you recommend in terms of changes for the VICP?

(A) The court spends far too much time looking for ways NOT to compensate families.[151]

(B) It should be overhauled.[152]

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146. Telephone Interview with K.N. and S.N., Parents of Vaccine Claimant (Aug. 18, 2010) (on file with authors as Case 59).

147. Telephone Interview with J.A. and E.A., Parents of Vaccine Claimant (Apr. 11, 2010) (on file with authors as Case 1); Telephone Interview with S.G., Parent of Vaccine Claimant (July 15, 2010) (on file with authors as Case 54); Interview with E.Z. and B.Z., Parents of Vaccine Claimant (2010) (on file with authors as Case 81).

148. Telephone Interview with E.Z. and B.Z., *supra* note 147.

149. Telephone Interview with J.A., Parent of Vaccine Claimant (Mar 13, 2010) (on file with authors as Case 27).

150. Telephone Interview with K.N. and S.N., *supra* note 146.

151. Telephone Interview with S.G., *supra* note 146.

> (C) There should be a program in place that would allow the court to reassess the children later in life to see if their needs have changed. This would make the life care planning less contentious and would allow for changes in laws, insurance coverage, and mostly the child's level of functioning. It is ridiculous to assume that you can adequately plan when a child is very young for every possible consequence of the vaccine damage throughout the child's life.[153]

The overwhelming majority of petitioners in the VICP have not received compensation. Of the 13,755 claims filed in the VICP to date, 2,621 awards have been paid, or less than 1 in 5 of the total number of claims filed. So far, 5,277 claims have been dismissed and 5,857 claims are pending. As most of the pending claims are in the Omnibus, they are likely to be dismissed.[154] The March 3, 2011 HHS Statistics Report notes that "HHS has never concluded in any case that autism was caused by vaccination."[155]

III. UNANSWERED QUESTIONS

In light of the strongly worded decisions in the Omnibus and the HHS Statistical Report noting that no case of vaccine-induced autism has ever been compensated, it is extremely puzzling to find so many cases of autism among VICP-compensated cases. While it is understandable that petitioners in these cases set out to prove encephalopathy and residual seizure disorder, and not autism, it also seems hard to understand that the Special Masters, experts, treating physicians, lawyers, and judges would all have been unaware of the presence of autistic symptoms in so many cases. To find eighty-three cases of confirmed autism among cases of confirmed vaccine-induced brain injury, with the

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152. Telephone Interview with E.Z. and B.Z., *supra* note 147.

153. Telephone Interview with K.N. and S.N., *supra* note 146.

154. *National Vaccine Injury Compensation Program, Statistics Report, March 3, 2011*, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/ statistics_report.htm (last visited Mar. 10, 2011).

155. *Id.*

likelihood that there may be many more among those compensated for vaccine injury, raises several questions:

(1) Were HHS and DOJ aware of the prevalence of autism diagnoses among those who have been compensated for encephalopathy and residual seizure disorder?

(2) What percentage of the remaining VICP-compensated cases of vaccine-induced injuries manifest autism?

(3) Is "autism" perhaps a different term for slightly less severe encephalopathy and residual seizure disorder? Is it possible that "autism" is a form of brain damage similar to acute encephalopathy and residual seizure disorder, but vaccine-induced brain damage all the same? This argument has been made for over two decades; unfortunately, the hypothesis has been inadequately studied.[156]

1. Likely Criticism

We anticipate lively critique of this preliminary assessment. Here are several of the most likely counterarguments:

(1) "Secondary autism" exists, but vaccines only "resulted in" autism and did not "cause" it.

Some may argue that vaccines indirectly caused autism as a result of other vaccine-induced brain damage. Whether autism is considered a secondary injury to encephalopathy and residual seizure disorder or a primary injury appears to be a semantic point having little legal significance. Under either theory, vaccines led to brain injury, and the VICP has compensated that vaccine-induced brain injury, including autism. In other words, HHS has been compensating certain expenses of vaccine-induced autism for more than twenty years, when labeled as "encephalopathy" and "residual seizure disorder," but not compensating it when labeled "autism" without cogent explanation.

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156. *See generally* HARRIS L. COULTER, VACCINATION, SOCIAL VIOLENCE AND CRIMINALITY: THE MEDICAL ASSAULT ON THE AMERICAN BRAIN (1990); *see also* BARBARA LOE FISHER, VACCINES, AUTISM & CHRONIC INFLAMMATION: THE NEW EPIDEMIC (2008).

(2) These individuals suffered from Dravet's Syndrome, a genetic disorder; they would have had the same outcomes without vaccination.

Vocal proponents of the U.S. vaccine program are likely to argue that many of these cases were wrongly compensated in the first place. They will argue that these brain damaged individuals suffered from a rare genetic condition called Dravet's Syndrome, and thus their seizures and encephalopathy shortly after vaccination were coincidental. For example, Dr. Paul Offit, prominent spokesperson for the U.S. vaccine industry, points to a single study by Dr. Samuel Berkovic of fourteen patients in Australia, funded by Bionomics "a productive drug discovery and development engine room focused on new treatments for cancer and serious disorders of the central nervous system."[157] Dr. Offit concludes, apparently on the basis of this one case series, that individuals who developed seizures within seventy two hours of vaccination would have developed their severe seizure disorders in any event because of their genetic mutations in the SCN1A gene.[158] Dr. Offit states:

> [A]fter Berkovic's paper, it was clear that all the time spent by parents to get health officials to admit that pertussis vaccine had permanently harmed children, all the money spent by pharmaceutical companies to compensate alleged victims, all the work of lawmakers to create a system to deflect lawsuits away from these companies, and all the ink devoted by the media to support these children and their parents had been an enormous diversion from the real cause of the problem.[159]

He concludes that parents were wrong to believe that vaccines were the cause of their children's epilepsy and mental retardation.[160]

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157. *About Bionomics,* BIONOMICS, http://www.bionomics.com.au/page.php?section=42 (last visited Jan. 19, 2011); *see also* A.M. McIntosh et al., *Effects of Vaccination on Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 LANCET NEUROLOGY 592 (2010).

158. S. F. Berkovic et al., *De-novo Mutations of the Sodium Channel Gene SCN1A in Alleged Vaccine Encephalopathy: A Retrospective Study*, 5 LANCET NEUROLOGY 465, 465 (2006).

159. DEADLY CHOICES, *supra* note 56, at 42-43.

160. *Id.* at 43.

While Dravet's Syndrome surely merits further study, to posit that a single drug company-sponsored study proves that all individuals who develop mental retardation or epilepsy (or encephalopathy and residual seizure disorder) in the immediate aftermath of vaccination would have developed it under any other circumstances strains credulity. Far more research would be needed, including large, population-based epidemiological studies, to conclude that vaccines played no role or even no aggravating role in the onset of such catastrophic symptoms.[161]

(3) Parents are poor reporters of their children's condition.

Critics will assert that parental caregivers are poor reporters of their children's conditions, subject to "confirmation bias." As a result, they will argue that these findings are not credible. Because of these concerns, we administered the SCQ to 27% of the total number of compensated families (and 35% of the cases having no published decisions) and found a high correlation between parental reports and scores for autism using this recognized screening tool. The accuracy of the autism assessment in the cases for which we have such corroboration suggests the likely accuracy of the parental reports for which we lack such corroboration. The authors would be delighted to have this study replicated with a more rigorous analysis of these and other compensated families, including full ADI-R diagnoses.

2. Recommendation: Congressional Inquiry

Autism is the most prevalent developmental disorder in the United States, conservatively affecting about one in one hundred and ten children.[162] This preliminary evaluation suggests that vaccine-induced encephalopathy and seizure disorder may be associated with autism. We recommend that Congress open an investigation of all compensated cases of vaccine-induced injury

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161. *See* Yuval Shafrir, *Vaccination and Dravet Syndrome*, 9 LANCET NEUROLOGY 1147, 1147-48 (2010), *available at* http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2802%2900160-6/abstract; Anne McIntosh et al., *Vaccination and Dravet Syndrome- Author's reply, Lancet Neurol.* 9 LANCET NEUROLOGY 1148, 1148-49 (2010), *available at* http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2810%2970289-1/fulltext.

162. Rice, *supra* note 73.

to find out how frequently this association occurs. Congress should find out what HHS, DOJ, and the VICP knew about the existence of autism as a characteristic of those compensated for encephalopathy and residual seizure disorder.

CONCLUSION

While there are likely many routes to "autism," including prenatal neurological insults and toxic post-natal exposures,[163] this preliminary analysis of VICP-compensated cases suggests that autism is often associated with vaccine-induced brain damage. It raises the question if the VICP's decisions have been fair to reject all claims of vaccine injury that use the term "autism." This preliminary assessment also suggests the possibility that other contemporary childhood neurological disorders, including attention deficit disorder and learning disabilities, might be less severe after-effects, on the same spectrum of vaccine-induced brain injury.

Based on this preliminary assessment, there may be no meaningful distinction between the cases of encephalopathy and residual seizure disorder that the VICP compensated over the last twenty years and the cases of "autism" that the VICP has denied. If true, this would be a profound injustice to those denied recovery and to all who have invested trust in this system that Congress created. This preliminary study calls for Congress to investigate the VICP and for scientists to investigate all compensated cases of vaccine injury to gain a fuller understanding of the totality of consequences of vaccine injury.

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163. *See* Marcel Kinsbourne & Frank Wood, *Disorders of Mental Development in* JOHN H. MENKES ET AL., CHILD NEUROLOGY 1097, 1112-21 (7th ed., 2006).

APPENDIX I

Diagnostic Criteria for 299.00 Autistic Disorder[164]

The following is from *Diagnostic and Statistical Manual of Mental Disorders: DSM IV*

(A) A total of six (or more) items from (1), (2), and (3), with at least two from (1), and one each from (2) and (3)

(1) qualitative impairment in social interaction, as manifested by at least two of the following:

a. marked impairments in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body posture, and gestures to regulate social interaction

b. failure to develop peer relationships appropriate to developmental level

c. a lack of spontaneous seeking to share enjoyment, interests, or achievements with other people, (e.g., by a lack of showing, bringing, or pointing out objects of interest)

d. lack of social or emotional reciprocity

(2) qualitative impairments in communication as manifested by at least one of the following:

a. delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime)

b. in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others

c. stereotyped and repetitive use of language or idiosyncratic language

d. lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level

(3) restricted repetitive and stereotyped patterns of behavior, interests, and activities, as manifested by at least one of the following:

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164. AM. PSYCHIATRIC ASS'N, *supra* note 70, at 75.

a. encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus
b. apparently inflexible adherence to specific, nonfunctional routines or rituals
c. stereotyped and repetitive motor mannerisms (e.g. hand or finger flapping or twisting, or complex whole-body movements)
d. persistent preoccupation with parts of objects

(B) Delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years:

(1) social interaction
(2) language as used in social communication,
(3) symbolic or imaginative play.

(C) The disturbance is not better accounted for by Rett's Disorder or Childhood Disintegrative Disorder.

APPENDIX II

VICP's Definitions of Encephalopathy, Seizure and Sequela[165]

Qualifications and Aids to Interpretation

(2) **Encephalopathy.** For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older,** an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

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165. *National Vaccine Injury Compensation Program, Vaccine Injury Table,* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., http://www.hrsa.gov/vaccinecompensation/table.htm (last visited Jan. 20, 2010).

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things). [ed. emphasis added]

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the

encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) **Seizure and convulsion.** For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) **Sequela.** The term "sequela" means a condition or event which was actually caused by a condition [*ed., i.e. a vaccine*] listed in the Vaccine Injury Table.

APPENDIX III

Excerpt of HHS Response to FOIA Request[166]

Health Resources and Services
Administration
Rockville, MD 20857

July 9, 2009
Freedom of Information Act (FOIA) Case No. HRSA 09-176

Dr. Mr. Krakow:

I am responding to your FOIA request for records regarding the Vaccine Injury Compensation Program (VICP). You requested the following items:

1. Records containing all decisions, including Special Masters written decisions and orders or other explanatory material, granting entitlement to compensation under the [VICP].
2. Duplicate of point 1.
3. All memoranda or other material evidencing the outcome of petitions filed with the [VICP].
4. All records containing statistics or other analysis of decisions granting or denying entitlement to compensation of petitions filed with the [VICP].
5. All records indicating criteria used by HRSA or related agencies to determine whether a vaccine injury claim should or should not be compensated.

Needless to say, this is an exceptionally large and complicated request that will be both costly and take a minimum of four to five years to complete. . . .

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166. *See* Letter from Thomas Flavin, Freedom of Info. Officer, Dep't of Health & Human Servs., to Robert Krakow (July 9, 2009) (on file with authors).

The costs are detailed in the attached receipt and total $754,625. If you will send us a deposit for half of the estimated costs – $377,312.50 – we will proceed with assembling and reviewing these records. **I must caution you that it will require at least 4 to 5 years to complete your request. . . .** .[*emphasis added*]

The Department of Health and Human Services' policy calls for the fullest responsible disclosure consistent with the requirements of administrative necessity and confidentiality which are recognized by the FOIA, 5 U.S.C. § 552, and the Department's implementing Public Information Regulations, 45 CFR Part 5.

If you require any further assistance, please call this office at (301) 443-28655.(*sic*)

Sincerely,
/s/
Thomas Flavin
Freedom of Information Officer

APPENDIX IV

Previous Studies using VICP Compensated Cases as Data

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
1993	Cowan et al.	IOM	"Acute encephalopathy and chronic neurological damage after pertussis vaccine," *Vaccine* 1993, 11(14): 1371-9[167]
1994	Prevots et al.	CDC	"Completeness of reporting for paralytic poliomyelitis, United States, 1980-1991. Implications of estimating the risk of vaccine-associated disease," *Arch. Pediatr. Adolesc. Med.*, 1994 148(5): 479-85.[168]
1996	Weibel & Benor	NVICP/USPHS	"Chronic arthropathy and musculoskeletal symptoms associated with rubella vaccines. A review of 124 claims submitted to the National Vaccine Injury Compensation Program," *Arthritis Rheum.*, 1996, 39(9): 1529-34.[169]
1996	Weibel & Benor	NVICP	"Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance between the CDC

167. Linda D. Cowan et al., *Acute Encephalopathy and Chronic Neurological Damage after Pertussis Vaccine*, 11 VACCINE 1371 (1993).

168. D. Rebecca Prevots et al., *Completeness of Reporting for Paralytic Poliomyelitis, United States, 1980-1991: Implications of Estimating the Risk of Vaccine-associated Disease*, 148 ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 479 (1994).

169. Robert E. Weibel & David E. Benor, *Chronic Arthropathy and Musculoskeletal Symptoms Associated with Rubella Vaccines. A Review of 124 Claims Submitted to the National Vaccine Injury Compensation Program*, 39 ARTHRITIS & RHEUMATISM 1529 (1996).

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
			and the National Vaccine Injury Compensation Program," *Am. J. of Public Health*, 1996, 86(5): 734-73.[170]
1998	Ridgway	Univ. of Calif., Berkeley	"Disputed claims for pertussis vaccine injuries under the National Vaccine Injury Compensation Program," *J. Investig. Med.*, 1998, 46(4): 168-74.[171]
1998	Weibel	NVICP	"Acute encephalopathy followed by permanent brain injury or death associated with further attenuated measles vaccines: a review of claims submitted to the National Vaccine Injury Compensation Program," *Pediatrics*, 1998, 101(3 Pt1): 383-7.[172]
1999	Ridgway	Lineberry Research Assoc.	"No fault vaccine insurance: Lessons from the National Vaccine Injury Compensation Program," *J. of Health Politics, Policy & Law*, 1999, 24(1):59-90.[173]

170. Robert E. Weibel & David E. Benor, *Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance Between the CDC and the National Vaccine Injury Compensation Program*, 86 AM. J. OF PUB. HEALTH 734 (1996).

171. Derry Ridgway, *Disputed Claims for Pertussis Vaccine Injuries Under the National Vaccine Injury Compensation Program*, 46 J. OF INVESTIGATIVE MED. 168 (1998).

172. Robert E. Weibel et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 PEDIATRICS 383 (1998).

173. Derry Ridgway, *No Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. OF HEALTH POL., POL'Y & L. 59 (1999).

Year	Authors	Institutional Affiliation	Article Title and Journal of Publication
2010	Atanasoff	U.S. HHS, HRSA, NVICP	"Shoulder Injury Related to Vaccine Administration (SIRVA)," Powerpoint presentation given to the Advisory Commission on Childhood Vaccines, Sept. 3, 2010.[174]

174. Sarah Atanasoff, Med. Officer, Health Res. & Servs. Admin., Div. of Vaccine Injury Comp.& Rosemary Johann-Liang, Chief Med. Officer, Health Res. & Servs. Admin., Div. of Vaccine Injury Comp., Presentation to the Advisory Commission on Childhood Vaccines (Sept. 2-3, 2010). For minutes of this meeting, go to http://www.hrsa.gov/vaccinecompensation/ ACCVMinutes-September2010.pdf.

APPENDIX V

Parent Structured Interview Form

National Vaccine Compensation Justice Project
Petitioner Parent Structured Interview Form

Case #: CD Child's Name: DOB:
Dkt.#: Special Master/Judge:
Mother's name: Father's name: Attorney name:
Guardian:
Address:

Telephone:
E-mail:
Mother's DOB: Father's DOB:
Siblings (gender and ages):

Mother's occupation at the time of filing:
Father's occupation at the time of filing:
Mother's occupation now:
Father's occupation now:

Status of Child
Subject child's present age:
Living situation: (With family, group home, etc.)
How is your child's life today?
What was the impact of the vaccine injury on your family?

Perceptions of Program Justice
In your opinion. . .
Was your child's claim resolved quickly?
Was your child's claim resolved with compassion?
Was your child's claim resolved fairly?
Has the Program met the needs of your child?

What were the positive aspects of the program?
What were the negative aspects of the program?
What would you recommend in terms of changes for the NVICP?
Would you be willing to write a letter describing your perceptions of the NVICP?
Would you be willing to speak publicly if given the opportunity?

Vaccine Injury - Encephalopathy
Does your child's vaccine injury induced encephalopathy include seizures?
Does your child's vaccine injury induced encephalopathy include an autism diagnosis, autistic features or autistic-like behaviors (which one)?
Does your child's vaccine injury induced encephalopathy include a diagnosis of Attention Deficit Disorder?
Does your child's vaccine injury induced encephalopathy include a diagnosis of Developmental Delay?

Vaccine Injury – Seizure Disorder
Does your child's vaccine injury induced seizure disorder include a diagnosis of Attention Deficit Disorder?
Does your child's vaccine injury induced seizure disorder include an autism diagnosis, autistic features or autistic-like behaviors (which one)?
When your child is not suffering from seizures, does the child exhibit autism-like behaviors?
Does your child's vaccine injury induced seizure disorder include a diagnosis of Developmental Delay?

Vaccine Injury Generally
Does your child's vaccine injury include myelin disorders?
Does your child also suffer from asthma, now or in the past?
Does your child have language difficulties?
Does your child have a diagnosis of CP?
Would you be willing to provide written material that verifies your child's diagnosis?
Would you be willing to release copies of your child's reports from medical experts (used only for verification purposes)?

Would you be willing to write a letter describing your child's medical condition?

Initial date of interview: Time:

Interviewer:
Follow up date:
Additional notes:

Follow up date:
Additional notes:

Estimated Vaccination Coverage* with Individual Vaccines and Selected Vaccination Series Among Children 19-35 Months of Age by State US, National Immunization Survey, Q1/2010-Q4/2010†

	3+DTaP¥	4+DTaP‡	3+Polio§	1+MMR‖	3+Hib¶	Hib-PS**	Hib-FS††	3+HepB‡‡	Hep B Birth dose§§	1+Var‖‖	3+PCV¶¶	4+PCV***	2+HepA†††	Rotavirus‡‡‡	4:3:1§§§	4:3:1:3‖‖‖	4:3:1:3-PS¶¶¶	4:3:1:4-FS****	4:3:1:3:3:1€	4:3:1:0:3:1€	4:3:1:3:3:1-PS€€	4:3:1:3:3:1-FS§§	4:3:1:4:3:1-€€	4:3:1:3:3:1:4€	4:3:1:0:3:1:4§§§	4:3:1:3:3:1:4-PS€€€€	4:3:1:4:3:1:4-FS§§§§
	95.0±0.6	84.4±1.0	93.3±0.7	91.5±0.7	90.4±0.9	92.2±0.8	66.8±1.3	91.8±0.7	64.1±1.3	90.4±0.8	92.6±0.8	83.3±1.0	49.7±1.4	59.2±1.4	82.0±1.1	78.8±1.2	80.3±1.1	62.2±1.3	74.9±1.2	77.8±1.1	76.3±1.2	59.2±1.3	70.2±1.3	72.7±1.2	71.5±1.2	56.6±1.3
	97.9±1.7	89.8±3.5	95.3±2.5	95.4±2.3	94.2±2.6	96.4±2.1	68.8±5.7	89.9±3.8	70.7±5.5	96.2±2.2	96.1±2.2	86.1±4.1	50.5±6.2	63.4±6.1	87.8±3.8	85.1±4.1	86.5±3.9	66.1±5.8	77.3±5.1	79.1±5.0	78.2±5.1	62.6±5.9	71.2±5.6	72.4±5.5	71.9±5.5	58.2±6.1
	91.2±3.6	79.1±5.5	90.4±3.7	88.4±3.9	87.1±4.4	92.6±3.2	78.8±5.4	91.8±3.4	71.2±6.0	83.5±4.8	89.2±4.1	75.7±5.9	44.7±6.8	47.1±6.8	76.7±5.7	75.0±5.8	76.3±5.7	68.4±6.3	70.2±6.2	71.9±6.1	71.4±6.1	63.6±6.5	65.0±6.5	66.1±6.5	65.9±6.5	58.4±6.8
	94.2±3.5	83.7±5.2	91.5±4.0	87.7±4.9	92.1±3.7	92.9±3.6	68.1±6.4	91.8±3.7	80.4±5.2	88.2±4.8	92.5±3.8	79.9±5.9	51.0±6.7	60.7±6.7	80.3±5.7	79.0±5.7	79.5±5.7	61.5±6.7	76.3±5.9	77.4±5.8	76.9±5.8	59.0±6.7	70.0±6.4	71.1±6.3	70.5±6.3	56.0±6.7
	93.2±3.9	82.6±5.1	91.8±4.1	90.5±4.2	90.5±4.2	90.9±4.2	61.4±6.9	93.7±3.5	82.4±5.0	91.9±4.1	91.7±4.1	79.5±5.8	34.2±6.4	48.5±7.0	82.0±5.2	80.0±5.5	80.4±5.4	59.5±7.0	79.3±5.5	81.2±5.2	79.7±5.5	58.9±7.0	73.2±6.1	74.5±6.0	73.6±6.1	56.3±7.0
	93.1±3.3	79.7±5.5	91.0±3.6	91.4±3.5	89.3±4.5	90.8±4.3	64.4±6.5	90.1±3.8	53.0±6.7	88.9±4.4	90.4±4.0	83.5±4.8	53.4±6.7	58.9±6.7	77.9±5.6	75.4±6.0	76.4±5.9	59.3±6.6	71.3±6.2	73.9±5.9	72.3±6.2	55.7±6.7	68.6±6.3	71.0±6.0	69.6±6.2	54.1±6.7
	93.9±3.2	86.0±4.4	92.6±3.4	89.3±3.7	87.8±4.7	89.2±4.6	69.2±6.4	90.9±3.4	57.6±7.0	85.7±4.3	91.0±3.6	81.6±5.4	42.0±6.7	55.0±7.3	82.3±4.8	77.4±5.6	78.8±5.6	64.1±6.7	71.3±6.1	76.3±5.4	72.8±6.0	59.8±6.9	65.7±6.5	68.3±6.4	66.9±6.5	56.2±7.1
	97.5±2.2	90.9±4.2	97.8±2.1	97.8±1.5	87.5±5.4	94.5±3.5	69.6±7.7	97.4±1.7	60.0±7.7	92.5±3.8	97.9±1.5	91.1±4.4	48.5±7.7	61.8±7.8	90.3±4.3	80.2±6.3	87.3±5.0	65.6±7.8	75.7±6.8	85.0±5.3	82.2±5.8	61.4±7.9	70.1±7.2	79.4±6.1	76.6±6.5	57.9±8.0
	97.6±1.8	88.3±3.9	95.3±2.5	94.0±3.0	92.2±3.3	95.4±2.4	67.1±5.9	89.5±4.0	69.3±5.7	94.5±2.5	97.0±2.1	87.9±4.3	62.0±6.0	82.1±4.8	85.6±4.3	80.7±4.9	83.9±4.5	61.4±6.1	72.9±5.6	76.8±5.3	75.7±5.4	56.2±6.2	68.1±5.8	71.9±5.7	70.8±5.7	54.3±6.2
ia	96.4±2.3	87.6±5.1	93.0±3.4	94.7±3.7	94.7±3.4	94.7±3.4	72.4±7.6	94.2±3.0	63.5±7.9	97.2±2.3	97.0±1.8	88.0±5.4	55.8±8.1	52.7±8.3	85.0±5.5	83.3±5.9	83.3±5.9	68.9±7.7	81.2±6.0	82.9±5.7	81.2±6.0	67.3±7.7	77.3±6.7	78.8±6.5	77.3±6.7	66.2±7.8
	97.6±2.2	92.2±4.1	96.2±2.5	94.1±3.0	94.3±4.1	94.3±4.1	76.0±6.5	96.1±2.5	52.3±7.9	95.4±3.2	94.5±3.6	88.1±4.9	49.6±7.9	59.7±7.8	89.6±4.4	87.5±5.0	87.5±5.0	72.7±6.6	85.8±5.1	87.0±5.0	85.8±5.1	71.4±6.7	79.9±5.9	80.5±5.8	79.9±5.9	68.2±6.9
	96.7±2.8	86.2±4.8	95.9±3.1	91.5±4.0	87.3±4.8	90.4±4.4	59.7±6.7	95.5±3.1	74.9±5.8	94.2±3.4	96.4±2.9	86.3±5.5	64.4±6.7	59.0±6.8	83.8±5.1	75.6±5.9	78.1±5.8	54.1±6.8	73.9±6.0	81.8±5.2	76.4±5.9	53.1±6.8	67.0±6.8	74.7±6.3	69.3±6.7	49.6±6.9
	94.0±3.1	85.9±4.5	92.5±3.3	93.2±3.3	86.7±5.0	88.1±4.8	71.6±6.1	89.0±4.4	71.5±6.0	92.4±3.4	91.1±4.2	83.0±5.3	44.9±6.4	52.1±6.5	83.7±4.8	78.9±5.7	80.1±5.6	67.7±6.3	76.0±5.8	79.1±5.6	77.2±5.7	66.1±6.4	72.9±6.0	76.0±5.8	74.1±5.9	63.7±6.4
	90.8±4.5	77.9±5.7	89.2±4.7	87.2±5.0	77.7±6.2	82.3±5.9	53.3±6.9	86.8±4.9	65.2±6.4	83.7±5.1	88.0±4.9	79.7±5.5	44.2±6.8	50.4±6.9	75.9±5.8	66.2±6.6	70.0±6.5	49.5±6.9	61.2±6.7	70.6±6.1	65.1±6.6	45.7±6.9	57.4±6.8	66.3±6.4	61.3±6.7	42.6±6.8
	97.1±1.4	85.3±4.1	95.9±1.9	90.5±3.2	91.2±3.2	93.7±2.9	69.5±5.4	93.5±2.6	66.1±5.2	89.0±3.6	96.1±1.7	87.1±4.0	45.2±5.5	60.3±5.5	83.5±4.2	80.5±4.4	81.9±4.3	64.7±5.4	75.9±4.8	78.7±4.6	77.4±4.7	60.7±5.5	72.4±5.0	75.1±4.9	73.9±4.9	59.5±5.5
	93.2±3.4	81.6±5.2	92.1±3.5	92.3±3.5	87.8±4.3	89.0±4.2	65.1±6.0	91.7±3.4	77.9±5.1	88.5±4.2	91.1±3.7	80.2±5.3	46.9±6.5	54.3±6.3	80.1±5.2	77.7±5.4	78.9±5.3	62.7±6.1	73.9±5.6	75.8±5.5	74.8±5.6	59.7±6.2	70.2±5.9	71.6±5.8	70.7±5.8	58.2±6.2
	96.4±2.9	84.6±5.3	95.3±3.5	93.8±3.7	89.1±4.5	94.8±3.6	63.9±7.1	93.7±3.8	52.3±7.2	92.7±3.9	93.5±4.3	87.6±5.4	55.8±7.2	66.1±6.9	83.8±5.4	78.8±5.9	83.6±5.4	59.0±7.2	77.3±6.0	82.4±5.5	82.1±5.5	58.4±7.2	72.7±6.7	77.8±6.3	77.5±6.3	57.7±7.2
	95.1±3.0	86.6±5.1	94.7±3.0	90.0±4.6	89.7±5.0	92.9±3.7	63.4±7.3	94.7±2.6	80.1±5.5	87.5±5.2	94.4±3.1	85.3±5.1	49.7±7.4	58.9±7.4	85.4±5.2	80.8±6.1	84.1±5.4	60.4±7.4	77.6±6.5	82.1±5.7	80.8±5.9	57.7±7.4	74.0±6.7	78.6±6.0	77.3±6.2	54.9±7.4
	93.8±3.4	83.1±5.5	93.1±3.6	89.5±4.1	85.2±5.3	88.1±5.0	62.0±6.6	93.2±3.3	83.3±4.9	92.3±3.4	90.5±3.9	77.7±6.0	45.6±6.4	57.5±6.7	80.9±5.7	74.7±6.1	77.4±5.9	58.7±6.6	72.5±6.2	78.7±5.8	75.2±6.0	56.9±6.6	64.2±6.5	68.9±6.4	66.8±6.5	51.8±6.6
	96.3±3.0	79.9±6.3	94.0±3.6	89.7±4.5	92.4±4.3	94.5±3.7	71.9±7.0	93.9±3.6	61.6±7.8	91.1±4.3	93.7±3.8	84.3±6.0	51.4±7.7	57.9±7.9	78.1±6.5	76.2±6.7	78.1±6.5	62.4±7.6	73.8±6.8	75.7±6.7	75.7±6.7	60.0±7.7	69.0±7.3	70.9±7.2	70.9±7.2	57.8±7.7
	94.6±3.7	86.6±5.6	92.4±4.1	90.9±4.5	85.3±5.4	90.6±4.6	55.4±7.7	86.6±5.4	72.0±6.5	87.2±6.0	90.7±5.1	81.6±6.3	27.2±6.6	42.1±7.7	83.4±5.9	77.0±6.5	82.0±6.1	52.2±7.7	70.4±7.3	76.8±7.0	75.4±7.1	46.2±7.7	67.0±7.5	72.7±7.3	71.6±7.3	44.0±7.6
	96.4±3.1	84.2±5.8	95.1±3.5	90.5±4.8	91.0±4.5	91.2±4.5	65.5±7.4	90.5±4.3	69.0±7.0	90.7±4.6	88.4±5.2	75.6±7.0	46.0±7.4	53.4±7.5	79.8±6.3	76.7±6.6	76.7±6.6	59.7±7.5	73.3±6.8	76.5±6.5	73.3±6.8	57.4±7.5	65.0±7.4	65.9±7.4	65.0±7.4	51.1±7.5
	97.7±2.9	91.0±4.3	95.6±3.4	92.3±4.3	95.7±3.3	96.2±3.3	73.7±6.4	95.8±2.5	67.3±6.5	91.5±3.9	95.9±3.3	90.4±4.2	51.1±7.3	70.9±6.4	86.7±5.2	85.8±5.2	86.3±5.2	68.5±6.8	79.9±5.9	80.9±5.9	80.4±5.9	63.5±7.0	77.2±6.1	78.1±6.1	77.7±6.1	61.6±7.0
	96.2±2.7	90.9±4.1	96.0±2.7	91.1±3.8	92.0±3.8	94.1±3.3	71.3±6.6	93.6±3.1	80.3±5.6	92.7±3.5	94.3±3.3	88.1±4.9	45.0±7.2	54.3±7.2	87.7±4.4	85.2±4.8	87.3±4.4	67.9±6.7	83.4±5.0	85.7±4.6	85.5±4.6	66.5±6.8	79.0±5.7	81.3±5.5	81.1±5.5	65.2±6.9
	94.2±3.5	87.8±5.2	93.7±3.6	92.7±4.0	89.9±4.3	94.1±3.5	63.4±7.3	89.5±4.3	46.8±7.4	91.1±4.1	95.4±2.9	88.7±4.9	49.3±7.4	67.4±7.2	85.2±5.6	80.2±6.1	84.4±5.6	57.9±7.3	74.3±6.5	78.4±6.2	77.9±6.2	53.9±7.3	71.6±6.7	75.7±6.4	75.1±6.4	52.5±7.3
	96.3±2.4	85.4±4.4	95.7±2.5	93.8±2.7	90.1±3.8	91.9±3.5	69.5±5.7	95.8±2.4	69.1±6.0	92.3±3.0	95.1±2.7	84.3±4.5	40.7±6.3	56.9±6.3	84.6±4.5	81.3±4.8	82.6±4.6	66.8±5.8	79.3±4.9	82.5±4.6	80.6±4.8	65.3±5.9	74.6±5.3	77.9±5.1	75.9±5.2	61.7±6.1
	92.6±3.4	80.3±5.2	89.9±3.8	90.4±3.9	87.8±4.4	90.8±3.7	64.1±6.4	89.2±4.0	64.8±6.5	86.7±4.4	87.8±4.3	76.2±5.6	44.4±6.5	59.3±6.4	78.4±5.4	75.6±5.7	76.9±5.5	61.9±6.4	70.3±5.9	73.1±5.7	71.7±5.8	58.1±6.4	65.5±6.2	67.9±6.0	66.8±6.1	55.3±6.5
	88.0±5.0	76.6±6.2	84.3±5.4	85.1±5.6	80.8±5.8	84.0±5.4	60.5±7.0	87.0±4.4	67.8±6.4	80.6±5.9	84.5±5.3	72.6±6.5	35.5±6.6	54.9±6.9	73.4±6.3	67.8±6.7	69.7±6.6	55.4±7.0	64.3±6.8	69.5±6.6	66.0±6.7	53.3±7.0	60.4±6.9	64.9±6.8	62.1±6.9	50.0±7.0
	96.8±2.3	90.1±4.1	93.7±4.0	94.2±3.3	90.0±4.5	92.9±3.8	74.1±6.6	91.6±4.2	66.7±6.9	90.6±4.4	95.4±2.9	90.4±4.2	60.3±7.1	73.2±6.6	88.0±4.8	83.4±5.5	86.1±5.1	70.6±6.8	78.9±5.9	83.4±5.3	81.6±5.5	67.2±6.9	76.6±6.1	79.9±5.8	79.3±5.8	66.3±7.0
	91.3±4.3	76.9±6.3	89.9±4.5	87.0±5.2	85.6±5.3	88.1±4.8	57.3±7.3	84.6±5.3	66.6±6.9	85.6±5.5	86.1±5.3	70.8±6.8	54.8±7.3	49.4±7.2	74.9±6.4	71.7±6.7	73.9±6.5	53.4±7.3	66.6±6.9	69.7±6.7	68.7±6.8	48.6±7.3	58.6±7.3	61.3±7.2	60.7±7.2	46.4±7.3
	99.5±0.7	92.0±5.1	97.8±2.0	95.8±3.0	99.5±0.8	99.5±0.8	75.1±6.7	97.2±1.8	62.6±7.8	92.8±4.5	99.2±1.0	93.2±4.0	59.7±8.2	73.1±7.3	88.1±5.8	88.1±5.8	88.1±5.8	68.3±7.4	84.1±6.1	84.1±6.1	84.1±6.1	65.4±7.5	81.0±6.5	81.0±6.5	81.0±6.5	63.3±7.5
	94.8±4.1	80.2±5.9	91.2±4.6	86.1±5.7	92.5±4.5	93.1±4.4	70.9±6.7	90.1±4.7	37.2±6.7	89.7±5.0	91.2±4.8	82.4±6.2	40.8±6.9	53.9±7.1	73.5±6.5	71.7±6.6	72.3±6.6	59.0±7.1	68.4±6.8	68.2±6.7	67.0±6.7	54.8±7.0	61.7±7.0	62.6±7.0	62.3±7.0	51.6±7.0
	93.5±2.9	78.3±5.5	91.1±3.5	88.8±3.8	88.6±3.9	90.3±3.6	64.5±6.3	91.2±3.3	60.0±6.3	88.9±3.7	90.1±3.7	78.2±5.5	51.1±6.6	53.9±6.6	76.0±5.6	73.0±5.8	74.5±5.7	58.8±6.5	70.9±5.9	73.8±5.7	72.4±5.8	56.8±6.5	65.4±6.2	68.3±6.1	66.9±6.2	53.1±6.6
	94.0±3.1	80.0±4.9	90.9±3.4	89.3±3.6	86.7±3.8	90.6±3.5	59.5±5.5	90.9±3.3	50.5±5.5	86.0±4.0	89.4±3.7	72.8±5.2	37.7±5.4	48.5±5.5	77.0±5.0	72.9±5.2	74.4±5.1	54.6±5.6	69.1±5.3	72.0±5.2	70.2±5.2	52.1±5.5	61.6±5.5	64.1±5.4	62.7±5.4	49.0±5.5
	96.9±2.3	87.5±4.2	96.9±2.3	94.5±2.9	87.6±4.2	92.9±3.3	59.9±6.2	93.7±3.2	75.0±5.8	94.1±3.0	96.8±2.3	87.5±4.3	48.1±6.5	69.6±6.2	86.2±4.3	80.2±4.9	84.8±4.4	57.2±6.3	77.0±5.2	82.9±4.7	81.6±4.8	55.1±6.3	71.2±5.7	77.1±5.4	75.8±5.5	52.1±6.3
	96.8±2.4	85.3±4.8	96.1±2.8	92.6±3.5	90.6±3.7	93.0±3.3	70.4±5.9	98.3±1.5	79.5±5.6	90.5±3.8	97.2±2.3	89.4±4.2	61.1±6.5	73.4±6.1	83.3±5.1	78.7±5.5	81.1±5.3	67.6±6.2	76.0±5.6	80.7±5.3	78.4±5.5	66.0±6.2	75.2±5.7	79.8±5.4	77.6±5.6	65.8±6.2
	96.0±2.8	84.3±5.9	94.9±3.1	93.6±3.5	92.2±4.0	94.0±3.4	70.6±7.3	94.8±2.9	73.5±7.1	89.7±4.9	92.5±4.0	81.8±6.3	46.2±8.1	57.2±8.3	82.0±6.1	79.6±6.4	81.4±6.1	67.0±7.4	76.0±6.8	78.4±6.4	77.8±6.4	63.9±7.5	73.8±6.8	76.2±6.6	75.6±6.6	62.5±7.6
	92.3±4.9	77.6±6.1	89.8±5.2	91.0±5.0	88.8±5.2	90.2±5.1	61.7±6.7	88.0±4.6	66.4±6.0	89.9±5.0	90.7±5.0	74.5±6.4	56.6±6.8	44.4±6.6	76.2±6.1	74.5±6.2	75.2±6.2	57.9±6.5	70.3±6.3	71.8±6.2	70.8±6.3	54.4±6.5	61.6±6.5	62.9±6.5	61.8±6.5	49.2±6.5
	96.3±2.5	83.7±5.0	92.8±3.3	92.8±3.3	87.7±4.6	92.4±3.9	61.3±6.7	91.9±3.4	61.7±6.4	89.4±3.9	94.0±3.2	87.7±4.4	55.6±6.8	52.8±6.9	80.8±5.3	74.1±6.0	78.8±5.6	56.1±6.8	69.3±6.3	75.8±5.7	74.0±6.0	53.4±6.8	67.0±6.4	73.4±5.9	71.6±6.1	51.9±6.9
	98.0±1.2	87.1±3.8	95.9±2.2	92.3±2.9	95.3±2.2	97.3±1.5	71.0±4.9	93.9±2.4	71.5±5.4	92.9±2.6	96.2±1.8	87.2±3.5	54.8±5.6	66.1±5.6	85.5±4.0	83.2±4.2	84.8±4.1	66.4±5.2	78.8±4.5	81.1±4.3	80.4±4.4	63.5±5.3	75.1±4.7	77.1±4.6	76.4±4.6	61.3±5.3
	98.5±1.4	85.8±5.7	98.5±1.4	95.8±2.7	86.7±5.6	90.5±5.0	67.2±7.7	97.6±1.7	69.7±7.5	93.2±4.2	96.2±3.3	82.3±6.9	54.2±8.1	76.7±7.3	85.0±5.7	76.6±6.9	78.0±6.8	62.3±7.9	75.3±6.9	83.7±5.8	76.7±6.9	61.0±7.9	68.9±7.6	74.1±7.4	70.3±7.5	56.6±8.0
	96.8±2.0	86.6±4.3	95.3±2.7	91.7±3.3	91.4±3.6	93.0±3.3	62.6±6.3	94.4±2.7	67.4±6.3	93.7±3.0	94.1±2.9	88.1±4.1	47.4±6.6	62.9±6.5	83.2±4.7	79.3±5.2	80.4±5.1	58.2±6.5	77.7±5.3	81.3±4.9	78.8±6.3	58.8±6.5	73.6±5.7	76.9±5.4	74.7±5.7	53.2±6.6
	95.2±3.1	80.1±5.6	94.7±3.2	92.1±3.6	89.2±4.4	90.1±4.3	58.8±6.8	95.9±2.4	62.4±6.8	91.0±3.8	90.9±4.2	76.4±6.1	33.1±6.6	46.8±6.9	77.9±5.9	75.2±6.0	75.5±6.0	54.6±6.9	73.2±6.1	75.7±6.0	73.5±6.1	52.6±6.8	65.4±6.7	67.0±6.7	65.7±6.7	48.7±6.9
	95.9±3.2	89.3±4.2	95.4±3.2	93.9±3.3	92.7±3.8	93.7±3.6	71.2±6.2	93.6±3.5	55.3±6.8	95.3±2.8	93.2±3.8	84.3±5.2	59.9±6.7	65.9±6.7	88.3±4.3	85.9±4.6	86.9±4.5	69.3±6.2	82.3±5.1	84.7±4.9	83.4±5.0	66.7±6.4	76.2±5.8	77.8±5.7	77.2±5.7	61.8±6.6
	93.3±2.0	83.9±3.3	91.9±2.1	91.8±2.4	90.6±2.6	91.0±2.6	69.2±4.2	88.4±2.7	69.6±4.2	90.2±2.5	91.4±2.6	83.0±3.3	54.9±4.4	61.9±4.4	81.7±3.5	79.6±3.7	79.9±3.7	65.6±4.4	74.8±3.9	76.5±3.7	74.9±3.9	61.2±4.4	70.1±4.1	70.9±4.1	70.3±4.1	58.6±4.4
	93.4±3.2	79.5±5.7	90.1±4.6	85.5±5.1	86.3±5.3	91.7±3.8	59.9±6.9	91.1±3.6	79.8±5.6	87.7±4.3	92.0±3.7	78.7±5.9	49.6±7.0	65.6±6.7	76.2±6.0	73.5±6.2	75.9±6.0	55.2±6.9	70.6±6.4	73.3±6.2	73.0±6.2	53.2±6.9	66.7±6.6	69.5±6.4	69.2±6.5	49.9±7.0
	96.9±3.0	86.0±4.8	94.4±3.3	92.7±3.3	90.4±5.0	90.4±5.0	52.1±7.1	91.7±3.7	21.4±5.9	82.9±5.0	92.7±3.5	84.2±5.6	38.0±6.8	51.8±7.1	82.4±5.1	79.4±6.0	79.4±6.0	46.2±7.0	71.0±6.5	72.8±6.3	71.0±6.5	41.4±6.9	69.0±6.6	69.7±6.6	69.0±6.6	40.6±6.9
	96.4±2.6	88.3±4.5	93.5±3.3	92.3±3.5	91.8±3.7	93.3±3.5	68.1±6.3	87.0±4.9	58.3±6.7	91.5±3.3	93.6±3.3	84.9±4.8	50.0±6.8	66.9±6.2	85.0±4.9	81.4±5.3	82.6±5.2	64.0±6.4	74.2±6.0	77.5±5.8	75.4±6.0	58.2±6.6	69.5±6.2	72.8±6.0	70.7±6.2	55.2±6.6
	93.2±3.0	81.9±4.9	92.0±3.2	89.8±3.6	90.9±3.4	91.3±3.3	63.9±5.7	90.8±3.3	77.3±4.9	85.7±4.1	91.6±3.3	82.9±4.4	44.9±6.0	50.4±5.9	80.3±5.0	79.6±5.0	79.6±5.0	60.7±5.8	73.7±5.4	74.0±5.4	73.7±5.4	57.2±5.9	70.9±5.5	71.2±5.5	70.9±5.5	55.7±5.9
	97.8±1.8	83.1±4.8	93.9±3.1	92.0±3.4	93.6±3.0	94.0±2.9	60.3±6.5	95.0±2.8	66.7±5.9	88.6±4.0	93.6±3.2	74.3±5.9	54.0±6.5	51.0±6.5	80.6±5.1	78.6±5.2	79.0±5.2	56.3±6.5	73.0±5.7	74.9±5.6	73.4±5.7	51.3±6.5	62.6±6.3	64.1±6.3	63.0±6.3	47.7±6.5
	93.9±3.5	88.8±4.7	91.5±3.9	93.2±3.3	91.1±4.0	92.7±3.8	76.6±5.7	91.9±3.6	61.4±6.9	91.5±3.7	93.1±3.6	88.4±4.9	52.1±7.0	64.7±6.9	86.5±4.9	84.0±5.2	85.6±5.1	72.5±6.2	81.7±5.3	84.3±5.1	83.3±5.2	70.4±6.2	80.1±5.5	82.7±5.2	81.7±5.4	69.7±6.2
	96.1±2.8	82.0±5.8	94.8±3.0	92.5±3.6	90.6±4.9	92.9±4.5	69.0±7.5	93.6±3.6	58.4±7.3	85.0±5.1	93.0±3.4	79.6±6.2	33.5±6.8	53.5±7.5	79.3±6.1	76.5±6.3	78.8±6.1	60.9±7.7	67.5±7.0	70.1±6.8	69.8±6.9	54.4±7.8	62.1±7.4	64.7±7.3	64.4±7.4	52.0±7.8
ıds	85.4±5.8	62.5±8.2	81.5±6.4	72.6±7.8	74.6±6.9	74.8±6.9	50.2±8.4	82.6±6.5	77.7±7.2	72.4±7.7	78.0±6.6	57.0±8.2	14.0±6.1	19.8±7.5	60.1±8.3	52.0±8.4	52.0±8.4	41.6±8.4	48.5±8.2	56.1±8.2	48.5±8.2	38.7±8.0	43.7±8.2	45.6±8.2	43.7±8.2	37.1±8.0

Q1/2010-Q4/2010 National Immunization Survey were born from January 2007 through July 2009.
ıs of any diphtheria and tetanus toxoids and pertussis vaccines including diphtheria and tetanus toxoids, and any acellular pertussis vaccine (DTaP/DTP/DT).
ıs of DTaP.
ıs of any poliovirus vaccine.
s of measles-mumps-rubella vaccine.
ıs of Haemophilus influenzae type b (Hib) vaccine.
Hib: ≥2 or ≥3 doses of Haemophilus influenzae type b (Hib), depending on brand type.
): ≥3 or ≥4 doses of Hib vaccine depending on product type received (includes primary series plus the booster dose).
ıes of hepatitis B vaccine.
ıes of hepatitis B vaccine administered between birth and age 3 days.
es of varicella at or after child's first birthday, unadjusted for history of varicella illness.
ıes of pneumococcal conjugate vaccine (PCV).
ıes of PCV.
ıses of Hepatitis A vaccine.
es of Rotavirus vaccine, depending on product type received (≥2 doses for Rotarix® [RVl] or ≥3 doses for RotaTeq® [RV5].

§§§ 4 or more of DTaP, 3 or more doses of poliovirus vaccine, and 1 or more doses of any MMR vaccine.
¶¶¶ 4:3:1 plus 3 or more doses of Hib vaccine of any type.
¶¶¶¶ 4:3:1 plus the primary series Hib.
**** 4:3:1 plus the full series Hib.
€ 4:3:1 plus 3 or more doses of Hib vaccine of any type, 3 or more doses of HepB vaccine, and 1 or more doses of varicella vaccine.
ç 4:3:1 plus 3 or more doses of HepB vaccine and 1 or more doses of varicella vaccine. Hib vaccine is excluded.
€€ 4:3:1 plus primary series of Hib vaccine, 3 or more doses of HepB vaccine, and 1 or more doses of varicella vaccine.
çç 4:3:1 plus full series of Hib vaccine, 3 or more doses of HepB vaccine, and 1 or more doses of varicella vaccine.
€€€ 4:3:1 plus ≥3 doses of Hib vaccine of any type, 3 or more doses of HepB, 1 or more doses of varicella vaccine, and 4 or more doses of PCV.
ççç 4:3:1 plus 3 or more doses of HepB vaccine, 1 or more doses of varicella vaccine, and 4 or more doses of PCV. Hib vaccine is excluded.
€€€€ 4:3:1 plus primary series Hib vaccine, 3 or more doses of HepB, 1 or more doses of varicella vaccine, and 4 or more doses of PCV.
ççç 4:3:1 plus full series Hib vaccine, 3 or more doses of HepB, 1 or more doses of varicella vaccine, and 4 or more doses of PCV.

tab03_antigen_state

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2/3/12

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Vaccinations Help Protect:

-Those who are unable to get vaccines due to medical reasons such as allergies, compromised immune systems, etc.
-Those that get the vaccine but are non-responders and therefore not protected
-You, me, our families, our friends, and even those who choose not to get vaccines

Unlimited Philosophical Exemptions:

-Only 20 states allow philosophical exemptions
-7 states (including California and Vermont) have "unlimited" philosophical exemptions, meaning that all cases are unconditionally granted
-Philosophical exemptions are associated with lower vaccination rates and Pertussis outbreaks
-No states have enacted legislation to ease or enable philosophical objections since 2003
-More than half of states have seen an increase in the rate of exemptions (medical, religious, or philosophical) over the past 5 years causing alarm
-In 2010-2011 Vermont had the second highest philosophical exemption rate for children entering kindergarten (Alaska was higher)
-Despite this rise, many states still have <1% of children exempted from vaccines

A Historical Perspective:

-Smallpox:
-First immunization program was started in MA in 1809 requiring Smallpox vaccination
- At one time Smallpox accounted for 10% of all deaths in the world, now eradicated

-Measles:
- In 1969, 29 states required certain immunizations for school admission after Robbins et al. released a study correlating active enforcement of mandatory immunization schedules with lower rates of Measles
-Cohort studies such as Salmon et al. and Feikin et al. show vaccine exemptors are 22-35 times more likely to contract Measles than vaccinated people
-Before the advent of a Measles vaccine, greater than 90% of all children in developed countries were infected with Measles by the age of 15
-1 in 30 with Measles will develop pneumonia while <2 in 1000 will die
-In 2000 Measles was 5th most common cause of death in children world wide
-In 2011 Europe had 26,000 cases of Measles with 9 deaths and 7,300 hospitalizations, >90% of infected people were unvaccinated or improperly vaccinated

-Hamoephillus Influenza
-1 in 200 children were infected by this bacteria prior to development of vaccine in the 1980's
-Currently less than 200 cases per year

-Polio
-Nearly eradicated
-2011 outbreak in China caused 1 death and 9 hospitalizations (China had been polio-free since 1999)

-Pertussis (whooping cough)

-Vermont had 90 reported cases of Pertussis in 2011 (likely underestimated)

-California had 10 children die last year; all but 1 hadn't received the 1st dose of immunization

-Study by Feikin et al. shows vaccine exemptors are 6 times more likely to contract Pertussis than vaccinated people, while schools with outbreaks had more exemptors than those without

-Study by Omer et al. also found an increase in Pertussis outbreaks in states that had an unlimited philosophical exemption policy—Vermont had the highest incidence of Pertussis amongst all states in this study!

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Up To Date

Clear Answers & Smart Advice About Your Baby's Shots

By ***Ari Brown, MD, FAAP***

Dr. Brown received her medical degree from Baylor College of Medicine in Houston, Texas; she did her pediatric residency at Harvard Medical School/Boston Children's Hospital. In private practice since 1995, Dr. Brown is perhaps best known as the coauthor of ***Baby 411: Clear Answers & Smart Advice for Your Baby's First Year*** (Windsor Peak Press).

In response to the recent media attention given to vaccines, autism, and other controversies concerning vaccines, the Immunization Action Coalition (IAC) has reprinted a special excerpt from *Baby 411* that answers these questions and more. IAC is grateful to Dr. Brown for these clear answers and smart advice, but mostly, we are grateful for her continued advocacy for safe and effective vaccines.

Vaccines. Autism. Controversy. As a new parent (or parent-to-be), it's hard not to hear the great debate in parenting circles these days—do vaccines cause autism? If not, what causes autism? Why is it on the rise? And what is autism anyway?

Let's start at the beginning—just what is autism?

What is autism?

Autism Spectrum Disorder (ASD) is really a collection of several disorders that have three abnormal areas in common: social skills, communication skills, and repetitive or obsessive traits. There's a broad range from mildly to severely affected. Specialists use the terms ASD and Pervasive Developmental Disorders (PDD) interchangeably. And, to get even more confusing, Asperger's syndrome, and "pervasive developmental disorder, not otherwise specified" (PDD-NOS) are other categories that fall under the ASD heading. Here is a brief explanation of each:

Autism Spectrum Disorder (ASD) or Pervasive Developmental Disorder (PDD): These terms describe the entire group of conditions that include autism, Asperger's Syndrome, and PDD-NOS:

- **Autism:** These children are the most severely impaired. They have little or no social and communication skills and have repetitive, obsessive behaviors.
- **Asperger's Syndrome:** These children have normal intelligence and language development but have trouble reading social cues and making conversation. Asperger's kids often obsess about certain interests.
- **PDD-NOS** (Pervasive Developmental Disorder—Not Otherwise Specified) is the default diagnosis for a child who has problems with social and communication skills, but does not fit into either of the above categories.

Autism affects one in 150 children. It is four times more common in males, and seems to run in families.

I've heard autism is on the rise. Why?

The first question we have to ask is, do we really have an epidemic or are more children just being diagnosed? Is it better detection due to better awareness? Are we displacing one diagnosis for another? Here are some explanations for the large rise in autism:

1. **Displacing one diagnosis for another.** In previous generations, many children were diagnosed with mental retardation, schizophrenia, or some other psychiatric disorder. Today, many of these same kids are diagnosed with severe autism.

   For example, in 1996, 1 in 63 kids were diagnosed with mental retardation (measured by an IQ score of under 70). Yet, in 2000, that number DROPPED to 1 in 83. Why? Were there suddenly much fewer kids with mental retardation? No, many of these kids are now diagnosed with autism instead of mental retardation.[1] In other words, autistic kids were there in the 80's and 90's—we just didn't call them autistic.

   In 1991, the Individuals with Disabilities Education Act (IDEA) required children with developmental disabilities to receive school services and be integrated into a mainstream classroom setting as much as possible. Autism was added as a new diagnosis for which a child could be eligible to receive educational services. In 1993, two years after this code was added, the Department of Education reported a 23% rise in autism. Prior to the coding change, kids with autism were often labeled with non-specific developmental delay, brain dysfunction, or mental retardation.

2. **Changing criteria, broader diagnosis.** The definition of autism has changed over the years. The Diagnostic and Statistical Manual of Mental Disorders (DSM) is the authoritative bible for psychiatric disorders in the U.S. The first two editions never even listed autism as a disorder.

   Dr. Leo Kanner first diagnosed autism in the 1940's. Yet it was not until 1980 when psychologists recognized autism. That's when the DSM for the first time listed criteria for diagnosis of autism.

   The autism diagnosis broadened again in 1994 when several more disorders were officially added to the DSM: Pervasive Developmental Disorder (PDD), PDD-NOS (not otherwise specified), Asperger's Syndrome, Childhood Disintegrative Disorder, and Rett's Disorder.

   By expanding the definition of autism, suddenly many more kids were declared autistic. Case in point: looking at recent autism diagnoses, up to 75% of these kids are high-functioning children with PDD-NOS or Asperger's.

   Unfortunately, many states don't break out where kids are on the autism spectrum. California's autism rate is often cited in the media as example of the "autism epidemic"—yet California doesn't specify where kids are on the autism spectrum, so it's hard to get solid numbers.

   Not long ago, kids who were smart but socially awkward had no diagnosis. Today, those kids are often diagnosed with Asperger Syndrome.[2]

3. **Better awareness, better and earlier diagnosis.** Popular diagnoses rise and fall like skirt lengths. Think about it—ten years ago, had you ever heard of Restless Leg Syndrome?

continued

When it comes to autism, this newfound awareness is actually a positive step. More people—parents and doctors alike—are on the lookout for children with autism.

Making a diagnosis and starting therapy earlier in life improves kids' longterm outcomes. But it also looks like autism is on the rise. Why? Because kids were previously diagnosed with autism after age five or six. Today, kids are diagnosed as early as 18 months of age. This adds many more kids to the rolls . . . but is autism really increasing? Or is there just an earlier diagnosis?

4. **Why does the U.S. have so many autism cases?** Autism is not just an American disease—it happens worldwide. But why do the U.S. and United Kingdom have such high autism rates? That's because the U.S. and U.K. have done the lion's share of research and studies into autism.

   Other countries are just starting to look into autism. For instance, in South Korea, kids are diagnosed with Reactive Attachment Disorder (RAD) . . which is really what we call Autism Spectrum Disorder (ASD) here in the U.S. We suspect that South Korea will report an alarming rise in autism when they figure out their RAD kids are the same as our ASD kids.

   And counting autistic kids is a relatively recent phenomenon. Before recent legislation led to schools labeling more kids as autistic, researchers just looked at either medical or school records to determine autism rates. This was imprecise to say the least.[3]

5. **Prevalence vs. Incidence.** If you've ever taken a statistics class (or tried hard to forget anything you learned if you did), here is a little review. Most of what we know about autism rates are based on prevalence studies: these are a sampling of a population at one point in time used to estimate overall rates. By contrast, incidence studies identify the ACTUAL number of autism cases over a period of time. The only way to know if autism is really an epidemic is to see a rise in the incidence of autism.

   Unfortunately, there are very few incidence studies of autism. That's because it is extremely difficult to do this research. Only one incidence study on autism is available—that 2005 report found that rates of PDD in the 90's were unchanged. So even though PREVALANCE studies seem to show autism is increasing, the incidence proof is lacking.[4]

6. **Social acceptance.** We've come a long way since autism was first identified as a disorder. Orignally, experts thought autism was caused by poor parenting—namely, the mother. These "Refrigerator Moms" were blamed for rejecting their kids, causing the kids to have social problems.

   Of course, this was WRONG. What we've learned over the past 70 years is that autism is not the mom's fault. But in the old days, no mother wanted their kid labeled autistic since that would imply HER guilt.

   Today, we realize it is not mom's fault—and thus parents are more willing to accept an ASD diagnosis. And the diagnosis now allows for special education services, which many parents realize can help their child.

7. **Over or misdiagnosis?** There is so much awareness now of Autism Spectrum Disorders, that perhaps clinicians are overdiagnosing it. One reputable study suggests that kids who actually have anxiety disorders, obsessive compulsive disorders, and personality disorders may be misdiagnosed now with ASD.[5]

   These are possible explanations for the "autism epidemic"—but we don't have all the answers yet. The bottom line: in the 1980's, one in 10,000 kids were diagnosed with autism. Today, it's one in 150. The U.S. is not the only country seeing this trend. Australia, Canada, Denmark, Finland, Iceland, Japan, and Sweden also report a disconcerting rise.

Okay, so what causes autism?

The million dollar question. There appear to be four chief suspects:

1. **Genetics.** We know genetics plays a role. Studying twins is an obvious way to detect genetic disorders. If one identical twin has autism, up to 96% of the time, so will the other twin. And siblings of ASD kids have a 5% risk of having an autistic disorder.[6] To date, the exact gene has not been identified, but it may reside on the X chromosome, which may explain the prevalence of autism in boys.[7] In fact, there is a genetic syndrome (called Fragile X) that is one known cause of autism.

   In 2008, researchers identified a specific gene in some kids with autism. This gene is involved in controlling brain cell communication.[8] It appears that some kind of mutation in this gene causes a risk of autism within families.

   Other researchers have found abnormalities on chromosomes of autistic kids. Hence it appears that autism is caused by several different genetic defects, although researchers haven't quite figured out the puzzle yet.[9]

   One study has shown that dads over the age of 40 have SIX times greater risk of having a child with an autistic disorder than dads who are younger than 30.[10] Hence, autism has eerie echoes of Down Syndrome, a genetic defect that is more common when a mother has "advanced maternal age" (over age 35).

   All of these studies show that genetic defects are a strong suspect in autism.

2. **Abnormal brain growth.** Although the cause is unknown, autistic children have problems with brain growth. Babies are born with immature brains that grow rapidly and make nerve connections called synapses...like an information superhighway. In the normally growing brain, some branches of this superhighway get "pruned." In the autistic child's brain, the pruning process is defective. This may explain why babies with autism have abnormally rapid head growth under one year of age. Boys with ASD seem to have higher levels of hormones (insulin-like growth factors), which may contribute to the larger head size, weight, and body mass index.[11]

3. **Environmental trigger.** Is there some environmental exposure that sets off abnormal brain development in a genetically predisposed baby? Maybe. And that exposure may happen at or shortly after conception—before a mother even knows she is pregnant. There is a critical period of fetal brain development that occurs at 20-24 days after conception where the brain is most sensitive to injury.

   Here are just a few theories that scientists are exploring as a cause for autism: flu exposure during pregnancy, and folic acid levels in Dad-to-be's sperm (possibly a too-high level can lead to problems). Studies done by the Environmental Working Group have found about 280 environmental toxins in umbilical cord blood—could one of these be a trigger?

   There is also a growing body of evidence that newborns who are later diagnosed with ASD already have abnormal levels of certain proteins in their brains. So, having an environmental trigger in the womb during a critical period of brain development seems a plausible explanation for autism.

   What about vaccines? There has been much talk about this theory, specifically that trace amounts of mercury used as a preservative in many vaccines prior to 2001 caused a spike in autism. We discussed this issue in depth in *Baby 411,* but just to sum up: the scientific evidence does not support this theory. Research during the past ten years

has taken a long hard look at vaccines and found conclusive evidence that vaccine exposure is NOT the turn-on switch for autism.[12] And no, despite what you might read online from fringe groups or plaintiff lawyers, there is no conspiracy among pharmaceutical companies to inflict autism on unsuspecting children.

The U.S. Centers for Disease Control and Prevention (CDC) has long-term studies underway to examine vaccines and autism. The most recent results, published in the *New England Journal of Medicine,* showed that the mercury preservative previously present in vaccines had no significant effect on either intelligence or developmental delays in kids ages seven to 10. The results of the CDC's study on mercury preservative and autism specifically will be published after this booklet goes to print. Stay tuned on our website for updates.

4. **Premature birth.** A recent study in the journal *Pediatrics* found that premature babies born at 25 to 26 weeks gestation have a 25% chance of developing an autism spectrum disorder.

BOTTOM LINE: Researchers don't know what causes autism, although the above factors provide clues. The goal is to find a way to PREVENT autism . . . but we aren't there yet.

Is it possible that autism is actually mercury poisoning?

No. Mercury poisoning, also known as Mad Hatter's Disease, is very different from autism. Symptoms of mercury poisoning include excessive sweating, tremors and kidney problems. Sufferers also talk and walk like they have had a stroke.

How do we know this? The information known about mercury poisoning comes from unfortunate communities that have experienced it. There is a large amount of data from the Faroe Islands, near Iceland. The people there would eat whale blubber contaminated with toxic levels of methyl mercury and polychlorinated biphenyls (PCBs). Children, especially those exposed as fetuses during their mother's pregnancy, seemed to have lower scores on memory, attention, and language tests than their unexposed peers.

Here's the rub: despite all those problems, these children with mercury poisoning were NOT diagnosed with autism.

Another key point: mercury preservative was taken out of required vaccines SEVEN years ago. But autism rates are still going up.

Did the mercury in vaccines cause autism?

No. Here is the scientific evidence:

- The Institute of Medicine spent four years studying this issue. Their conclusion, issued in 2004: mercury preservatives in vaccines did NOT cause autism . . . and the Institute said it was time to move on to look at other possible causes. Several other leading medical organizations (both nationally and internationally) agree with this conclusion.
- Mercury preservative (thimerosal) was removed from vaccines commonly given to infants and young children in the U.S. in 2001, but the rates of children being diagnosed with autism are still skyrocketing. A survey of autism rates in California in 2008 confirms that mercury is out and autism rates are still going up.[13] If thimerosal was the cause of autism, and it was taken out SEVEN years ago, autism rates should be going down by now. That's because autism spectrum disorders are usually diagnosed by three years of age.
- Mercury preservatives were removed from vaccines in Denmark in 1992. Canada and the European Union have followed suit. Their autism diagnosis rates are still going up, too.

  Mad Hatter's Disease (mercury poisoning) and autism are very different disorders, as discussed above.
- A study of 100,000 kids in England compared those receiving mercury-containing vaccines to those who did not. The ones who had the mercury-free shots had HIGHER rates of autism.
- A study in 2007 showed that children between seven and ten years of age who got those mercury containing vaccines (before 2001) had no significant differences in tests of attention and processing information.[14] Although the study did not look specifically at autism, it showed that mercury preservatives did not make much of an impact on brain functions in general.

Do vaccines still contain mercury? What about the flu vaccine?

In 2001, the FDA required manufacturers to discontinue using mercury preservative for ALL routine childhood vaccines. Period.

Many vaccines, like that for measles, mumps and rubella (MMR), have NEVER contained mercury preservatives. Nor is mercury used in the production process for MMR. However, there are four vaccines on the market that still use mercury preservative in the manufacturing process—the mercury is then REMOVED from the final vaccine.

Because the flu vaccine is reformulated each year for the upcoming season, manufacturers need to move as efficiently as possible to produce large quantities of vaccine. The best way to do this is to produce vaccine in multi-dose vials, which requires a preservative. There are, however, single-dose preparations that are FREE of mercury preservatives that can be given to young children and pregnant women, if available.

Let's do a reality check here: a tuna sandwich has FIVE TIMES more mercury than one dose of flu vaccine.

As a doctor, I am much more concerned about mercury exposure in the environment—particularly in food (like that tuna fish sandwich). So if you are worried about mercury exposure, consider this: there's mercury in breast milk.

A baby gets 25 times more mercury by breastfeeding for six months than in a single dose of flu vaccine. Breast milk contains between 1.4 and 1.7 micrograms of methyl mercury per liter. If you assume that a baby is breast-fed exclusively up until six months of age, that baby will consume about 360 micrograms of methyl mercury. That's twice the amount of mercury that was ever contained in vaccines and 25 times the quantity of mercury contained in the influenza vaccine.

A quick chemistry lesson: certain compounds have completely different properties even though they have similar sounding names. For instance, there are TWO types of mercury: methyl mercury and ethyl mercury. The type of mercury that has raised health concerns is methyl mercury. Methyl mercury is a small molecule that can get into the brain and takes almost TWO MONTHS to break down. High concentrations of methyl mercury can be found in tuna, swordfish and shark from contaminated waters.

Now, let's contrast that with ETHYL mercury, which is/was the type of mercury used in vaccine preservatives. Ethyl mercury (thimerosal is an example) is rapidly eliminated from the body within a WEEK. Compared to methyl mercury, ethyl mercury is a much larger molecule that cannot enter the brain.

Ideally, it would be nice to remove ALL mercury preservatives from flu vaccines—so we could put this controversy to rest. The problem: at this time, the only way to manufacture the huge quantity of flu vaccine needed each year requires using mercury preservatives. Hopefully, vaccine makers will figure out a way to eliminate mercury from all vaccines in the future—so any concerns can finally be put to rest.

What do you think of delaying vaccines or using an alternative vaccination schedule?

The CDC publishes a recommended vaccine schedule for all children

in the U.S.—this schedule wasn't created from thin air . . . doctors, scientists and researchers work together to decide what is the best time to give shots. The goal: protect as many babies as soon as possible from deadly disease.

Now, one of the popular myths about autism is that somehow kids are getting "too many shots, too soon." Despite the scientific evidence that shows vaccines do NOT cause autism, some parents think that if they space out their kids' vaccines in an "alternative schedule" this is somehow safer.

Adding to this notion are blogs, books, and web sites that promote alternative vaccine schedules, delaying critical shots months or years after a child can safely receive them.

Here's a nasty little truth about alternative vaccination schedules: they are all fantasy. There is absolutely no research that says delaying certain shots is safer. Doctors who promote these schedules are simply guessing when to give which shots.

What we know for certain is that delaying your child's shots is playing Russian Roulette. The simple truth is you are leaving your child unprotected. Who knows what disease (preventable from a simple vaccine) will crop up next? Deadly diseases like measles are only a plane flight away.

Also: spreading out vaccinations creates new challenges. Live vaccines must be given at least four weeks apart to mount an active immune response. Take the MMR (measles, mumps, and rubella) vaccine—your child could get one combo shot and take care of all three deadly diseases at once. If you get three separate shots, however, it would take at least three months (because each is a live vaccine). That leaves kids unprotected until the series is completed.

When families demand a spaced out vaccination schedule, this is what I tell them as their doctor: "At the end of the day, I just want your child vaccinated. If you want to give two shots today and two next week, that's okay. Just come back. And promise me you will do it in a timely manner (that means you return in weeks, not months or years, to finish vaccination)." The goal: make sure the child is protected.

One important point to remember: despite all the media attention to this subject, very few parents actually choose to delay or opt out of vaccinations.

Are vaccines really necessary?

Yes. As a doctor, I am greatly worried when parents decide to delay or not to vaccinate their child. That's because vaccine-preventable diseases are real.

I have watched a child die from a vaccine-preventable disease while I helplessly stood by. I've cared for several babies gasping for breath with whooping cough. These diseases kill children. Respect them. Last year alone vaccines prevented 14 million infections and 33,000 deaths in the U.S.

Our grandparents remember diseases like polio. And how folks lined up to get vaccinated. Yet, you've probably never even heard of anyone with polio today. The great irony of vaccine success is that parents today are unfamiliar with the diseases they prevent.

In the past 10 years, I have seen two forms of bacterial meningitis basically disappear, thanks to vaccines. Before the HIB (*Haemophilus influenzae* type b) vaccine was developed, there were about 20,000 U.S. children a year who suffered or died from this infection. Now there are less than 200 cases per year. Before the pneumococcal conjugate vaccine, which protects against streptococcal meningitis, 17,000 American children per year had invasive infections with strep. And, about 200 kids died of this each year. Since vaccination, serious infections have been reduced by 90%. That's pretty amazing.

And no, you can't just let everyone else vaccinate their kids—and let them protect your un-vaccinated child.

Just look at the recent measles outbreak in 2008 in San Diego. It all started with a child, who was unvaccinated by parent choice. He returned from a trip to Switzerland with measles. He went on to infect TEN other unvaccinated children—his siblings, school friends, and three babies who were too young to be vaccinated who were exposed to that child in a doctor's waiting room. Of the 11 cases, one baby was hospitalized.

And this outbreak may be a trend. During the period January through July of 2008, the highest year-to-date cases of measles were reported in the U.S. since 1996: 131 cases from 15 states and the District of Columbia. Over 90% were unvaccinated or had unknown vaccination status and two-thirds of these cases that were eligible for vaccination were not vaccinated because of philosophical or religious beliefs. There were also 16 babies who were too young to be vaccinated. Babies, who are the most vulnerable to serious infection, do rely on other vaccinated children in the community to protect them when they are not old enough to be immunized.

So, when people argue that kids get too many shots today, I ask them if they'd rather their child get meningitis. And what about vaccines in the pipeline? If we've already got too many shots, would you decide to skip a future vaccine to prevent HIV? Probably not. That's because you know that vaccine might be the one that saves your child's life.

Didn't the government recently concede that vaccines caused autism?

As you may have heard on the news, the government recently decided to compensate a child whose autism was allegedly triggered by a vaccine. Here's the background behind the headline:

The Vaccine Injury Compensation Program has been holding special hearings called the Omnibus Autism Proceedings. This "Vaccine Court" is looking at allegations that 4900 children developed autism from vaccines. The court is first looking at nine cases to form opinions about the evidence.

One child, Hannah Poling, was awarded a monetary settlement. Hannah was born with a rare genetic disorder (mitochondrial disorder, which is a dysfunction in basic cell metabolism). This is the equivalent of being born with an undetected heart defect—a ticking time bomb that could go off at any time.

For rare kids like Hannah, any stress could have caused her to develop autism. In fact, having a vaccine-preventable disease like the flu or chickenpox could have far worse health consequences—a disease like that could have killed her. Although she was not diagnosed prior to being vaccinated, experts recommend that even children with known mitochondrial disorders still be vaccinated.

So even though the headlines screamed that (in this case) a vaccine caused autism, the facts of the case show this isn't true. Hannah's underlying disease caused her deterioration and autism. The case was settled and determined that it did not represent a test case for the 4899 other children.

Experts on mitochondrial disorders do NOT think this disease is the "smoking gun" that triggers autism. That's because many folks have similar dysfunctional cells but never become autistic.

And there is no simple test for mitochondrial disorders. Instead, you must do a difficult and painful muscle biopsy and a spinal tap. As a result, testing all kids for mitochondrial disorders is not necessary, ethical or practical. And even if your child is diagnosed with a mitochondrial disorder, the recommendation is still to vaccinate.

Does the MMR vaccine cause autism?

One small study of only eight patients in 1998 led a British research

group to conclude that the combination MMR vaccine might cause autism.[15] But in March 2004, after questions were raised about the study, 10 of the 13 researchers of the study withdrew their claim of having found a possible connection between MMR and autism. They said, "In this paper, NO CAUSAL LINK was established between MMR vaccine and autism as the data were insufficient...now is the appropriate time that we should together formally retract the interpretation of the data suggesting a link."[16]

Numerous major studies (at least 17 so far) since 1998 also soundly refute this alleged link. The most prominent: the Institute of Medicine's 2004 report clearly dispelled any link between MMR and autism.

Perhaps the most compelling argument that the MMR vaccine does NOT cause autism is Japan—in 1993, that country stopped using the combination MMR vaccine. Instead, Japanese children were given three separate shots for these diseases. Despite this change, autism rates in Japan continue to rise.[17]

The hysteria surrounding the MMR vaccine and the false 1998 report did have one serious consequence in England: a sharp rise in measles, mumps, and rubella after parents stopped giving their kids the vaccine. In 2004, only 80% of children in the U.K. were vaccinated against MMR. And look at the rise in cases of mumps: 1995: 1936 cases; 2003: 4265 cases; 2004: 15,503 cases.

And remember, autism rates are rising in the U.K. as well. So, now they've got both autism AND vaccine-preventable diseases. It's a lose-lose battle—and the casualties are kids.

Here's the bottom line: as a doctor who sees a large volume of kids, I have never seen a perfectly normally developing kid walk into my office, get his MMR vaccine . . . and come back next week with autism. It doesn't happen.

Are we giving too many vaccines today, too soon?

More vaccines are actually a GOOD thing! Every new vaccine protects more kids from getting sick . . . expensive hospital stays . . . and perhaps death or permanent injury. More kids are prevented from getting devastating diseases than ever before, thanks to vaccines. What about getting several shots at once? Is that dangerous? Could you overload a child's immune system with these vaccine germs?

Look at it this way: your child is exposed to thousands of germs on a daily basis (even if he is not in daycare). Exposing your child to five or eight different germs in the form of vaccines is a spit in the bucket. And young kids have a better immune response to vaccines than older children and adults.

Before a vaccine is approved for use by the government, its safety is extensively studied. These studies look at how kids respond to the vaccine. And so-called "combo" vaccines that incorporate several shots at once also consider the combined effect. Even if your child got 11 shots at the same time, he would need to use only about 0.1% of his immune system to respond to the vaccines.

The goal is to protect your child as quickly as possible from diseases that are very dangerous to young children.

And even though the number of shots has gone up, the actual load on the immune system has gone down. That's because today's vaccines are "smarter" and better engineered than the shots from a few decades ago.

Case in point: whooping cough. Before 1991, the whooping cough vaccine had 3000 different germ particles (antigens). Today's whooping cough shot has just three to five particles—just as effective, but much better designed to be easy on your immune system.

Before 1996, the polio vaccine was "live"—this carried a small risk of actually getting polio. Today's polio vaccine is dead (inactivated) . . . and carries NO chance of transmitting the disease.

So, here's the irony: YOUR parents took much greater risk when getting vaccinated back in the 50's, 60's, and 70's. Today, even though we have many more vaccines, the risk is much lower.

Our children are really getting smarter, safer vaccines today and better protection than we ever got as kids.

BOTTOM LINE: Vaccines do not weaken the immune system, they boost it.

Are there other toxins in vaccines that could cause autism?

Are there additives in the vaccines? Yes. And you should know about them.

Vaccines contain the active ingredients that provide immunity. However, there are inactive ingredients that improve potency and prevent contamination. Here is a list of additives and why they are there.

1. **Preservatives**—prevent vaccine contamination with germs (bacteria, fungus): 2-phen-oxyethanol, phenol.
2. **Adjuvants**—improve potency/immune response: aluminum salts.
3. **Additives**—prevent vaccine deterioration and sticking to the side of the vial: gelatin, albumin, sucrose, lactose, MSG, glycine.
4. **Residuals**—remains of vaccine production process: formaldehyde, antibiotics (neomycin), egg protein, yeast protein.

Now, after reading the above list, you might be freaking out—aluminum salts? MSG? Formaldehyde? We should point out that only TRACE amounts of most of these additives are in vaccines. None have been proven harmful in animals or humans in these amounts.[18]

Reality Check: Should vaccines be "greener"?

If vaccines contain ingredients like aluminum or formaldehyde, wouldn't it be better if vaccine makers got rid of these additives?

We agree that this sounds reasonable—but it doesn't mean that current vaccines are UNSAFE.

Here's the key point: additives like aluminum in vaccines are in EXTREMELY SMALL amounts (often, just a trace). We are all exposed to *significantly higher* levels of environmental toxins in our everyday activities.

Let's look at aluminum. Babies ingest 50 micrograms of aluminum per liter of breast milk . . . and 500 micrograms of aluminum per liter of formula. By contrast, the amount of aluminum in a vaccine is much smaller.

Do you wear antiperspirant? That's got aluminum in it too. And aluminum is found in most food, soil, and water. So, to avoid aluminum exposure, you'd have to stop wearing antiperspirant—and basically leave the planet.

And aluminum poisoning does not cause symptoms of autism, either.[19] Trace amounts (far less than what your baby eats everyday) of aluminum improve the body's immune response to some vaccines. That's why it is in there.

Why is formaldehyde in vaccines? Well, small amounts sterilize the vaccine fluid so your child doesn't get something like the flesh-eating Strep bacteria when he gets his shots.

If you use paper towels or mascara, or have carpeting in your home, you've been exposed to formaldehyde. Obviously, exposure to large amounts of formaldehyde is not a good thing for anyone's health. But, again the amount in vaccines is extremely small.[20]

BOTTOM LINE: Vaccine additives are there for a reason—to make them safer and more effective.

There's so much anti-vaccine stuff online—it's hard to know whom to believe. Can doctors be trusted on this issue?

Most pediatricians are ALSO parents—and docs dedicate their life to protecting kids. If I ever thought vaccines were harming kids, I'd change what I do. I vaccinated my own kids and would do it again in a heartbeat. If you have any doubt about vaccinations, just ask your pediatrician if she vaccinated her kids.

How do you explain the parents who claim their child was perfectly normal and then "something happened"?

It seems like just about everyone's heard one of these heart-wrenching stories—whether it be a child with autism that you know personally, or a celebrity's kid you hear about on TV. The parent reports that the child was developing just fine, until one day the lights just went out. Often, that phrase is accompanied by "after he got his shots."

And understandably, it's enough to make any other parent freak out and think twice when it's time to vaccinate his or her own child.

About 50% of parents with a child affected with autism spectrum disorder believe it was triggered by vaccination. However, the other 50% do not think vaccines had anything to do with it.

Here is what I think, based on what I see in my own practice. Autistic kids were never "typical" to begin with. Not one patient of mine who has ASD was perfectly normal, got a vaccination, and returned the next week with autism. In fact, all the parents in my practice whose children have ASD tell me that they either a) did not recognize the early differences in their child's development or that b) they always knew something was different about their child. The signs just became more apparent over time, the milestones stagnated, or the child seemed to lose skills. About one in five parents will report a loss of milestones. That's what brings it to the parent's attention.

An important fact: above, we noted that one in five parents report a loss in milestones. That means that a vast majority (80%) of kids diagnosed with autism spectrum disorder have no loss of milestones. They start out on a different developmental path and the symptoms become more apparent over time.

One of my ASD patient's moms, who is a medical professional, told me that she realized how clearly different her son's early development was after she watched her second child, without ASD, breeze through her developmental milestones. She had no frame of reference with her first child. And since just about every parent has a camcorder these days, the developmental differences early in a child's life are easily chronicled on videotape for developmental specialists to review. They say the same thing I do. The child was never perfectly normal and these, sometimes, subtle differences are seen before a year of age.

Heck, even the most vocal autism mom of all, Jenny McCarthy, who claimed on Oprah that her son was normal until receiving his combination measles-mumps-rubella vaccine, admits in her book that she missed the early signs of her child's ASD. Specifically, she said that it took her child until he was five months old to smile at her, when her friend's babies all smiled by two months.

One of the leading autism experts in the country has told me that there are, indeed, an extremely small number of ASD children who have completely normal milestones and then regress, which is known as "late onset autism." This type of autism likely represents a subset of children who have a distinct genetic abnormality that turns off spontaneously without any trigger at all. And this distinct group deserves genetic testing and more research.

I know, I know, who are you going to believe? Don't I trust parents and their instincts? Absolutely—you know your kids better than anyone else. But having a child diagnosed with autism is a highly emotional experience. And the diagnosis is usually made around the same time a child is going through his vaccination series. It's true . . . but unrelated. It's true that vaccinations are happening, and it's true that developmental differences become apparent. That doesn't mean they are related. Toddlers are also wearing diapers, drinking whole milk, and hanging out with parents who use cell phones. Do diapers cause autism? How about cell phones or milk? Obviously, no.

And let me be clear, parents aren't the only ones who miss the early signs of autism. Pediatricians do, too. Full developmental assessments are often three to four hours in a specialty referral center. We rely heavily on parents to point out their concerns. Parents and doctors can both miss early signs of autism spectrum disorders in the first year of life. This is one of the key reasons why the American Academy of Pediatrics created an Autism Toolkit in 2007 for its doctors to learn the signs, screen specifically for autism at every well child visit, and provide resources and educational materials for affected children.

BOTTOM LINE: Stoking parents fears about vaccines with false rumors about safety is irresponsible and creates a lose-lose situation for society—and the casualties are children.

Vaccines work. And they are safe. Rather than demonize vaccines, we (doctors, parents, researchers, the government) should put our time, effort, and money into researching the CAUSES of autism and the best possible treatments.

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DR. GABRIEL ARCHDEACON 2/3/12 7
S.199

Tree of Life Medicine
Dr. Gabriel Archdeacon
174 River St. • Montpelier, VT 05602 • 802-505-0597 • 707-440-4703 fax

February 3, 2012

S.199 Testimony

I am Dr. Gabriel Archdeacon and I am a Naturopathic Doctor in Montpelier, Vermont. I am testifying today at the request of my patients, and am offering my opinions as an individual doctor. I am neither representing my profession as a whole nor any organization.

I see patients of all ages in my practice and have a large pediatric population. I administer vaccinations most every day. Many of the families I work with are very upset by S.199 and I share their concerns. Unfortunately the issue of vaccination is very divisive among doctors, communities, and families. I have read the summary of testimony offered last week and have listened carefully to the testimony of my colleagues this morning. I am not going to discuss vaccine safety or the risks associated with the communicable diseases vaccines aim to protect against. You have heard a lot about these two sides of the story. Instead I am going to offer you information about the choices people are making and why the Philosophical Exemption is important in allowing them to make these choices. Ultimately the health of the children, families, and the community I serve is my primary objective.

1. The Philosophical Exemption is crucial to allow parents to make educated and rational decisions for their family.
   a. Most states, including Vermont have a "Religious Exemption" for vaccines.
   b. Because it is not carefully scrutinized, parents across the country use this exemption whether it truly applies to them or not.
   c. These families mostly choose to do no vaccinations
      i. Because the religious exemption does not allow you to be religiously opposed to some and not others.
      ii. And because their choice often alienates them from pediatricians and the health care system.
   d. The Philosophical exemption allows parents to work with a doctor they trust. The doctor and the parents are able to discuss the families unique set of risk factors, fears, and concerns regarding infections and the associated vaccinations.
2. Many people do not want to vaccinate their children at all.

a. A significant number of the families who come into my office are concerned over the potential side effects of vaccinating their children and question the necessity of many of the vaccines.
b. Many of them do not want to do any vaccinations and eliminating the Philosophical exemption will not change the choice they make.

3. Counseling and establishing trust works.
   a. I spend significant time counseling parents about these infections and the vaccines that aim to prevent them.
   b. There are a variety of risk factors for each of the infections and many families in Vermont have a very low cumulative risk.
   c. As a result of our discussion, many families who would have otherwise avoided all vaccinations choose to vaccinate their children against some of the most dangerous infections.
   d. Unfortunately a growing number of Pediatricians and Family Physicians are choosing not to have these conversations with their patients. Even worse, many of these doctors are telling their patients that if they choose to stray from the conventional vaccine schedule they must find a different doctor.
   e. I regularly get new families transferring to my practice who went to their child's two month wellness visit and had a very negative experience when they tried to ask questions about vaccinations.

The Philosophical Exemption is an important right for Vermont's families. The issue of vaccinations is very controversial and divisive. Both sides have drawn lines in the sand. The solution is not to take away the rights of parents to make choices for their children, they know and understand the specifics of their unique situation better than any doctor. The solution is to encourage doctors to engage parents about this issue, to have respectful conversations about individual circumstances, and by sharing their medical expertise help the parents to make the choices that are best for their family. As a doctor who is concerned about the health of our children, families, and communities I encourage you to vote no on S.199.

Sincerely,

Dr. Gabriel Archdeacon

Child's Last Name: ... Sex: | Parent/Guardian Name (please print):

Parent/Guardian, please choose the exemption(s) that apply to your child below.

☐ Temporary Medical Exemption
☐ Permanent Medical Exemption

_____ Until _____
Vaccine(s) Date (or Permanent)

Print Name of Licensed Health Care Provider (MD, DO, ND, PA, ARNP)

X _____ X _____
Signature of Licensed Health Care Provider Date

☑ Personal/Philosophical Exemption (see Box 1)
☐ Religious Exemption (see Box 1)
☐ Religious Membership Exemption (see Box 2)

I do not want my child to get the following vaccine(s):

☐ Diphtheria	☐ Hepatitis B	☐ Hib
☐ Measles	☐ Mumps	☐ Pertussis (whooping cough)
☐ Pneumococcal	☑ Polio	☐ Rubella
☐ Tetanus	☐ Varicella (chickenpox)	

☐ Other (indicate):

Box 1

Provider Statement: "I, Dr. Provider, am a qualified provider (MD, DO, ND, P.A. ARNP) licensed under Title 18 RCW. I confirm that the parent or guardian signing in Box 3 (Parent/Guardian Statement) has received information on the benefits and risks of immunization to their child as a condition for exempting their child for medical, religious, personal, or philosophical re asons."

X Dr. Provider
Signature of Licensed Health Care Provider (MD, DO, ND, PA, ARNP)

X July 22, 2011
Date

Box 2

Parent/Guardian Demonstration of Religious Membership: "I am a member of a church or religious body whose beliefs or teachings do not allow for medical treatment from a health care practitioner. By supplying the information requested below, no further proof or signed provider statement in Box 1 is required for this religious exemption."

X _____
Name of Church or Religious Body

X _____ X _____
Signature of Parent or Guardian Date

Box 3

Parent/Guardian Statement: "I certify that all the information provided on this certificate is correct and verifiable. I understand that if there is an outbreak of a vaccine-preventable disease my child has not been fully immunized against (as indicated above, for medical, personal/philosophical or religious reasons), my child may be at risk for disease and can be **excluded** from school, child care, or preschool until the outbreak is over."

X Maria Parent/Guardian
Signature of Parent or Guardian

X 7/22/2011
Date

If you have a disability and need this document in a different format, please call 1 -800-525-0127 (TDD/TTY 1-800-833-6388).

[1] RCW 28A.210.080-090 states that before or on the first day of every child's attendance at any public and private school or licensed child care center in Washington State, the parent or guardian must present proof of either: (1) full immunization, (2) the initiation of and compliance with a schedule of immunization, as required by rules of the State Board of Health, or (3) a certificate of exemption, signed by a parent or guardian and a licensed health care provider.

[2] A letter may substitute for a signed 'Provider Statement' on this certificate. To be accepted, the letter must reference the child's name on this certificate, confirm that the child's parent or guardian got information on the risks and benefits of immunization to their child, and be signed by a licensed health care provider.

MARTHA ISAACS 2/3/12 S.I.S.

MARTHA ISRAEL 2/3/12 S.199

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Testimony: VT. Senate Committee on Health and Welfare 2/3/12
Martha Israel RN MEd. NCSN, Rumney Memorial School Nurse, Middlesex

As a school nurse I am obviously a really big proponent of immunizations, but I am not in support of S.199 (or H.527). I don't believe that we should refuse to educate children because we disagree with the medical decisions of their parents.

I understand the genesis of school immunization laws: in the mid 1800s there were outbreaks of life threatening diseases such as small pox and the most effective way to identify and vaccinate children was through the school system. But this is 2012. We no longer have the same imminent threat of fatal diseases and we no longer need schools to locate and reach families. Thanks to Dr. Dynasaur every Vermont child can have health insurance and a physician - and school nurses insure that every child has a medical home. I believe the parental decision to immunize should be shifted from the school nurse to the medical community - where it belongs. This change will be a more effective way of increasing the immunization rates than this Bill to get rid of the philosophical exemption.

I suggest Vermont adopt the approach that Washington State took last year. They amended their Immunization Law to require that a child's health care provider sign off on the Philosophical Exemption Form. The provider is not signing that he or she agrees with the decision, but that the parent has received comprehensive education and had a discussion about the risks of not immunizing. Those parents who are choosing the exemption based on misinformation or fear will hopefully reconsider - and we will not be punishing the children of those caring parents who truly believe that immunizations are harmful. I have included a copy of Washington's Exemption Form in my written testimony.

I work in an elementary school with a significant number of philosophical exemptions. In my experience I have found that if I develop a good relationship with these parents, earning their trust and educating them about the medical facts around immunizations, many of them eventually do decide to immunize - especially when they meet other parents who have vaccinated. I believe we can actually increase the percentage of immunized children by embracing rather than isolating these families.

I get a real visceral reaction when I think about the fact that in Vermont we would consider refusing to educate our children in our public schools because we don't agree with the medical decisions of their engaged, concerned and loving parents.

Thank you for your time and attention.

KATIE MURPHY 4/3/12 S.179
10

Written Testimony in Support of Repealing the Philosophical Exemption to Vaccination

Katie Murphy, PharmD, BCPS, BCACP
Clinical Pharmacist
Assistant Professor of Pharmacy Practice, Albany College of Pharmacy & Health Sciences

Since the development of the first vaccine (smallpox) in the late 1700s, the incidence of vaccine-preventable disease and deaths due to these diseases has decreased dramatically. In fact, it is a testament to the success of vaccines that we are having conversations about the "controversy" of immunizations today—vaccines are a "victim" of their own success! The public perception of the severity and susceptibility of vaccine-preventable diseases decreases as their memory of these diseases (due to the success of vaccines in preventing them!) decreases.[1] At the same time, the controversy and public concern about vaccine-related adverse events has increased.

Herd immunity is what happens when the vaccination of a large portion of a population provides a measure of protection for people who do not have immunity. Herd immunity is absolutely dependent on high vaccination rates, in order to break the "chain" of infection. If a community like Vermont has high rates of unvaccinated children, we are putting our children at risk of diseases with potentially terrible consequences. Not only are we putting those unvaccinated children at risk whose parents declined for "personal" reasons, but also those children who cannot be vaccinated for valid medical reasons—and these are often kids with chronic, serious medical conditions who are *most* susceptible to experiencing the serious complications of diseases. Even vaccinated children are at higher risk when we lose this herd immunity, since vaccines, like all medications, cannot be 100% effective all the time.

Multiple studies have shown an increase in the incidence of vaccine-preventable diseases when there is a higher percentage of people refusing vaccinations due to exemptions (mostly non-medical).[2,3] By weakening the "herd immunity" and allowing exemptions based on rumor and myths we are failing not only these susceptible children but also our entire community.[4-6]

Misconceptions and mistruths that may be cited as reasons for refusing vaccines include the idea of the immune system becoming "overloaded" or overwhelmed (this has been refuted scientifically[7]), vaccines causing autism (this controversy started with a study in *just 12 children* who received the MMR vaccine[8]—this study was later completely discredited (and withdrawn from the medical journal) due to egregious violations in study protocol and falsehoods on the part of the investigator that were discovered. Since then, multiple large-scale, well-designed studies with thousands of patients have not confirmed any such autism-vaccine link.[9-14] Another concern is the "mercury" that vaccines contain. Thimerosal is a vacccine preservative and contains 49% ethylmercury, which is a substance similar to mercury but one that actually behaves much differently from the naturally occurring environmental neurotoxin methylmercury. Thimerosal has been removed from all vaccines administered to infants (as a precautionary stance, not due to any evidence of its harm), except for some influenza vaccines. Regardless, no relationship has been found between thimerosal and autism in multiple population studies over many decades conducted in the United States, Denmark, Sweden, Canada, and the UK.[15-24]

In fact, the incidence of autism actually *increased* in Denmark, Canada, and California after thimerosal was removed from vaccines.[20-22]

Like all medications, vaccines do have the potential for side effects and adverse events. But like all medications, you have to consider the risk and the benefit. The benefit of vaccines is their effectiveness (not 100%, but very high—typically above 90% for most vaccines) at preventing serious disease—millions of people are spared the effects of devastating diseases that used to kill thousands of children and adults. The vast majority of adverse events from vaccines are minor and transient—reactions like a slight fever or a local skin reaction. Serious adverse events like seizures or anaphylaxis do happen, but are very rare and should be weighed against the risk of infection. For example, a child who has been "exempted" from receiving the measles vaccination is 35 times as likely to contract measles as a child who has been vaccinated.[25] Measles is a highly contagious disease that can lead to pneumonia, encephalitis (a serious inflammation of brain tissue) and even death. The risk of potentially deadly measles complications like encephalopathy is *1000 times* higher than the risk of encephalopathy from the measles vaccine (1 in 1 million).[26]

As a pharmacist, I am lucky to be in the position to help increase immunization rates in Vermont. By law, I can give a needed immunization to an adult patient, so that they don't have to make the extra trip to the doctor's office or clinic or, worse than that, *not* make the trip and remain susceptible to a disease. Pharmacists are the healthcare professional that is most accessible to the public! People like me become pharmacists not to get people to take more medications or receive more vaccines—we become pharmacists to help people live longer, happier, healthier, more productive lives. And we need to promote and encourage people to take medications and vaccines that are *appropriate* and will *achieve* this goal.

We need to optimize immunization rates in Vermont to protect our entire community. If we do not, we are putting our children, our parents, our neighbors, ourselves at risk of the serious consequences. Let's dispel the myths and non-truths, focus on the science, and keep Vermonters healthy and informed.

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From: "Every Child By Two" Website:

"There are actual, achievable measures that could be taken to immediately improve preschooler immunization rates. It is time for us to redouble our efforts to protect the 20 percent of preschoolers who are routinely not being immunized on time" Rosalynn Carter

According to the Centers for Disease Control and Preventions National Immunization Survey, in 2008 immunization coverage levels of 90 percent or better for five of the eight vaccines (Polio, Measles/Mumps/Rubella (MMR), *Haemophilus influenzae* type b (Hib), Hepatitis B, and Varicella) were achieved. The estimate for the 4:3:1:3:3:1 series (4 doses of Diphtheria/Tetanus/Acellular Pertussis (DTaP), 3 doses of Polio, 1 dose of MMR, 3 doses of Hib, 3 doses of Hepatitis B, and 1 dose of Varicella) was 76.1% which was a slight decrease from the 2007 estimate of 77.4% . Coverage levels of Hib decreased from 92.6% in 2007 to 90.9% in 2008. This was most likely due to the shortage of Hib vaccine which resulted in a recommendation to defer the routine Hib vaccine booster dose administered at age 12--15 months.

"Preschoolers are particularly vulnerable to a host of childhood illnesses. No child in America should have to get sick from vaccine-preventable diseases."
Rosalynn Carter

As many as 22 percent of preschool-aged children are not receiving all of the recommended routine vaccinations which protect against a range of common childhood diseases. Despite the fact that from 2006 to 2007 there was a 0.5 percent increase in the number of fully immunized preschool-aged children, each year an estimated one million of these children are still not fully immunized on time. Leaving a single child unprotected is not acceptable in this affluent nation.

Preschoolers are particularly vulnerable to a host of childhood diseases and therefore, are most in need of comprehensive, preventive vaccinations. However, this is the age group with the lowest immunization rates.

One of the positive observations from the survey is that among racial/ethnic groups, coverage estimates varied little. In fact, after the results were adjusted to account for poverty, the coverage estimates were not significantly lower for any ethnic group when compared with whites. While this lack of racial/ethnic disparity in vaccine coverage levels is a positive observation from the survey, the gap in coverage levels that persists between children who live in poverty and those who do not means that the struggle to overcome barriers to accessing preventive health care among children living below poverty is far from over. We must continue in our efforts to reduce contributing cost issues such as those associated with vaccine administration, well-child visits, transportation, and lost time from work if we wish to overcome the poverty barrier and increase the overall immunization coverage rates.

From a variety of perspectives, including medical and financial, the public benefits when *all* children are vaccinated. High vaccination rates are one of, if not our most important safeguard against the spread of epidemics. Numerous cost-benefit analyses show that vaccination against the most common childhood diseases delivers large returns on investment -- saving $16.50 in medical costs and indirect costs, such as disability, for every $1 spent on immunization[1].

Ensuring that all children have access to the full series of immunizations in a timely manner is achievable. Closing the vaccination gap should be high on our list of national health priorities.

Childhood Vaccines Save Lives and Money

- Routine childhood immunization
  - 33,000 deaths prevented annually
  - $43 billion saved annually

Disease	Cases Prevented	Deaths Prevented
Diphtheria	247,212	24,721
Tetanus	146	22
Pertussis	2,614,874	1,008
Polio	60,974	723
Measles	3,433,036	2,794
Mumps	2,095,917	11
Rubella	1,784,030	14
CRS	602	66
Hib	17,469	661
Hepatitis B	207,353	3,024
Varicella	3,788,807	57
Total	13,622,004	33,101

For every $1 spent:	
DTaP saves[2]	$27.00
MMR saves[3]	$26.00
H. Influenza type b saves[4]	$5.40
Perinatal Hep B saves[5]	$14.70
Varicella saves[6]	$5.40
Inactivated Polio (IPV) saves[7]	$5.45

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From: "Every Child By Two" Website

Immunization Success

Over the course of the twentieth century and into the twenty-first, vaccines have been developed to reduce the incidence of devastating vaccine-preventable diseases. Immunization policy in the U.S. currently focuses mainly on children, as vaccine-preventable diseases can strike young children who are most susceptible to their consequences. Laws requiring that children be immunized prior to entering school, which were initiated among the states during the Carter Administration, have pushed immunization coverage rates to near universal percentages among school-aged children (95 percent for school-aged children.) iv

Immunization is one of the most successful public health achievements of the 20th Century. Due to systematic programs, smallpox has been eliminated worldwide, and cases of polio, measles, pertussis, diphtheria, and Hib are at all-time lows. The burden of other diseases has been significantly reduced.

According to one study, the standard childhood immunization series prevents approximately 10.5 million cases of infectious illness a year and 33,000 deaths in the United States.v Another report published by the World Health Organization, UNICEF and the World Bank found that three million lives are saved worldwide each year through childhood immunizations -- a number that could be doubled with increased funding.vi

Smallpox: Varying strains of smallpox disease have been identified, each extremely infectious and leading to skin lesions, permanent scarring, and serious illness. Depending on the strain, fatality rates run as high as 25 percent to less than one percent.vii Smallpox is immunization's greatest success story to date, as this dreaded disease has been eradicated. As of the early twentieth century, tens of thousands of smallpox cases were reported in the U.S. each year.viii The last case of smallpox in the U.S. was reported in 1949, and routine vaccination of American children ended in 1971. The last case of smallpox in the world occurred in Somalia in 1977.ix In 1980, scientists officially declared that vaccines had been successful at eradicating smallpox worldwide.

Polio: Before polio vaccine was available, the U.S. had 50,000 polio cases a year, including 13,000 to 20,000 cases of paralytic polio. These annual epidemics of polio often left thousands of victims -- mostly children -- permanently in braces, crutches, wheelchairs, and with iron lungs.x Immunization has eliminated the disease in the U.S. and Western Hemisphere, and the World Health Organization had set a goal of eradicating polio worldwide by the end of 2004. However, Nigeria's northern State of Kano suspended polio immunization in August 2003 amid rumors that the vaccine was contaminated

with HIV and that it caused infertility. Consequently, polio cases reemerged in Nigeria and other previously polio-free countries. Polio immunization has restarted in Kano and the WHO now estimates that polio can be eradicated by the end of 2005.xi

Measles: Measles is one of the most infectious diseases in the world; more than 90 percent of people who are not vaccinated will get measles if they are exposed to the virus. In the U.S., roughly one in five who develop the disease require hospitalization for one or more complications.xii Before 1963, more than three million cases of measles and 500 deaths from measles were reported each year. More than 90 percent of children had measles by age 15.xiii Widespread introduction of vaccine has resulted in a reduction of measles incidence from 894,134 cases in 1941 to 89 cases in 1998 and 44 cases in 2002.xiv, xv

Pertussis: Pertussis (also known as whooping cough) can be a severe illness, resulting in prolonged coughing spells that can last for many weeks or even months. In children, the disease often leads to vomiting and can interfere with efforts to eat, drink, and breathe; children often suffer dehydration and lost weight, and infants are prone to pneumonia, brain damage, seizures, and mental retardation.xvi Before pertussis immunization was available, nearly all children developed whooping cough. The CDC reports that following the introduction of immunization in the mid-1940s, pertussis incidence declined more than 99 percent by 1970 and to an all-time low of 1,010 cases by 1976. However, since then, an increase in incidence of the disease has been documented, with more than 10,000 cases reported in 2003 and outbreaks occurring every three to four years. Furthermore, some researchers have estimated that only one-third of pertussis cases in the U.S. are actually reported. xvii

Diphtheria: Diphtheria is a serious bacterial disease that frequently causes heart and nerve problems. The death rate is five percent to 10 percent, with higher death rates (up to 20 percent) in the very young and the elderly. In the 1920s, prior to regular immunization, there were 100,000 to 200,000 American cases of diphtheria each year and 13,000 people died from the disease.xviii Since the introduction of immunization, diphtheria has dramatically declined from a high of 206,939 reported cases in 1921 to one in 2002. xix, xx

***Haemophilus Influenzae* type B (Hib)**: Before Hib vaccination, *Haemophilus influenzae* type B caused serious infections in 20,000 children each year, producing meningitis (12,000 cases) and pneumonia (7,500 cases), bacteria in the blood, and inflammation of the epiglottis.xxi Hib meningitis killed 600 children each year, and left many survivors with deafness, seizures, or mental retardation. Since introduction of conjugate Hib vaccine in December 1987, the incidence of Hib has declined by 98 percent. xxii The number of cases of serious Hib disease in children under five years of age reported in 2002 was 331.xxii

Rubella: While rubella is usually mild in children and adults, up to 90 percent of infants born to mothers infected with rubella during the first trimester of pregnancy will develop congenital rubella syndrome (CRS), resulting in heart defects, cataracts, mental retardation, and deafness. Expectant mothers are now routinely tested for rubella antibodies during pregnancy. From 1964-1965, before routine rubella immunization, there was an epidemic of 12.5 million cases that resulted in an estimated 20,000 infants born with CRS; 2,100 neonatal deaths; and 11,250 miscarriages. Of the 20,000 infants born with CRS, 11,600 were deaf, 3,580 were blind, and 1,800 has mental retardation. Due to the widespread use of rubella vaccine, only 18 cases of rubella and one case of CRS were reported in 2002.xxiv

Hepatitis B: National studies show that about 12.5 million Americans have been infected with hepatitis B virus at some point in their lifetime. Over 10 percent of these individuals develop chronic infection, increasing chances for chronic liver disease, cirrhosis, and liver cancer. An estimated 20 to 30 percent of such cases stem from infection during childhood. Approximately 5,000 people die each year from hepatitis B-related liver disease resulting from chronic hepatitis B. However, with the recent advent of vaccine, the number of new infections per year has declined from an average of 450,000 in the 1980s to 7,996 in 2002.xxv The greatest decline has occurred among children and adolescents due to routine hepatitis B vaccination.xxvi

Tetanus: Tetanus, commonly known as Lockjaw, is a severe disease that causes stiffness and spasms of the muscles and is often fatal. The larynx (throat) can close causing breathing and eating difficulties, muscles spasms can cause fractures (breaks) of the spine and long bones. Some people go into a coma, and die. Approximately 30 percent of reported cases end in death. From 1922-1926, there were an estimated 1,314 cases of tetanus per year in the U.S.xxvii In 2002, as a result of extensive immunization, only 25 cases of tetanus were reported.xxviii

Mumps: While usually a mild disease, mumps can produce swelling of the brain, nerves and spinal cord which in some cases leads to paralysis, seizures, and fluid in the brain. Moreover, in children, it is a major cause of deafness. Prior to immunization, the U.S. suffered approximately 200,000 cases per year. After vaccine licensure in 1967, reports of mumps decreased rapidly, but brief resurgences, such as an epidemic in 1987 that led to a reported 12,848 cases occurred. Since then, a second dose of mumps vaccine was added to the standard childhood MMR series and as a result, annual cases are now in the hundreds rather than the thousands.xxix

Varicella: Although generally mild, varicella (chickenpox) virus can lead to severe illness causing complications such as secondary bacterial infections, severe loss of fluids (dehydration), pneumonia, central nervous system irregularities, and shingles. The virus is highly contagious and thus virtually all

unimmunized individuals contract varicella if exposed to the virus, usually prior to adulthood. Before immunization, the U.S. reported an estimated four million cases a year, leading to approximately 11,000 hospitalizations and 100 deaths. A new chickenpox vaccine was licensed in 1995, and incidence of the disease is now declining.xxx Chickenpox can be particularly dangerous to a developing fetus. Pregnant women who have never had chickenpox are at risk of contracting chickenpox during pregnancy. A small percentage of women who get chickenpox in the first or second trimester can have babies with birth defects known as "congenital varicella syndrome." In addition, chickenpox may be more severe in pregnant women than in others putting the woman at risk of severe complications. Vaccinating close contacts of a susceptible pregnant woman is the most effective way to protect her from disease.xxxi

Influenza: Influenza is a serious disease. In an average year, the flu causes 36,000 deaths and 114,000 hospitalizations in the United States. While the majority of deaths resulting from flu occur in the elderly, rates of infection are highest among children and hospitalization rates among children zero-to-one year old are similar to those of the elderly.

Agatha Kessler - Oppose S199!

From: "Allison" <allisonpar@aol.com>
To: <akessler@leg.state.vt.us>
Date: 2/6/2012 8:32 PM
Subject: Oppose S199!

Dear Agatha,

Here is my written statement as per our conversation on the phone yesterday afternoon. As I said, I was hoping to read this at what I thought was the public hearing last Friday.

I can't tell you how much your taking the time to talk to me meant. You were so professional and calmed some of the concerns I've been carrying around since I got word of this bill. They (we) are very lucky to have you in this position! Keep up the fabulous work.

With gratitude,

Allison

Please oppose S.199 and H.527. I have spent a lot of time researching this issue and what I have found is a sea of gray area, which does not lend itself to black and white mandates. This is an issue of freedom concerning our family's health of which I can think of nothing more personal.

Whether you decide to vaccinate or not, there are risks. There is evidence that choosing either way could find you safe, or find you filled with regret. Because of this place, this point of having to decide which option am I most willing to go? Which consequences would I better be able to live with? This is so personal and certainly not a place for government to dictate.

I understand vaccine manufacturers have total liability protection for injuries and deaths caused by government mandated vaccines. Our families are being asked to assume all the risk, and in the event of an adverse reaction to a vaccine, pay all the consequences. How can we sit by and accept a mandate to do something to our children that goes squarely against our natural instincts of what is best for them, while knowing that the issuers assume no risk? And there is the issue of how each individual vaccine has varying degrees of benefit vs. risk. Again, not conducive to a one size fits all formula. And what of the vaccines in the pipeline? It is no secret that pharmaceutical companies are busy "improving" current vaccines as well as working to add more to an already too heavy schedule. What of the cumulative effect of all these shots on our children's young systems? These companies have nothing but more money to gain by every vaccine added to the CDC schedule. Doesn't it make sense to be protective of our children that they not be used as guinea pigs and/or revenue for these companies? Please be careful in setting a precedent that does not keep these coming vaccine introductions in mind.

I moved here from New Jersey. I have chosen to have and raise my children HERE in Vermont because I have revered this state for its history and commitment to honoring individual freedoms and self-reliance. This proposed bill is what I thought I had left behind. This legislation could drive families with young children out of Vermont, to a place where health is recognized and respected as a personal

issue.

In my circle of friends with families, we have varying opinions and degrees of where vaccines fit in with our personal situations. But where we all agree is that the choice should be ours to make. We are not numbers. We are people with families making informed decisions about what we put in our bodies. *Our bodies. Our choice.* In the words of Mayor Bloomberg of NYC, "Politics have no place in health care".

Allison Parrish

Montpelier

JENNIFER STELLA 2/3/12 S.199

Statement from

Jennifer R. Stella, B.S. Microbiology, Homeopath, 2/3/2012

Ladies and Gentlemen of the Vermont Senate Health and Welfare Committee, I thank you for your hard work and dedication and for allowing for me to speak today.

I hold a **microbiology** degree from the University of Massachusetts, Amherst. I spent a decade in the field of infectious disease diagnostics marketing before starting my family and staying home to raise my two children. I now work as a homeopath in Waitsfield.

My decision not to vaccinate my children was - as it should be for everyone - an intense personal journey that began after my son had an adverse reaction to his shots at 2.5 months old. For those of you not familiar with the immunization schedule – there is a copy in your packet (***Exhibit 1***).

If you look at the VT schedule you will see that today we are asked to administer over 20 vaccines to children by 18 months. My son had his adverse reaction after his first round of shots. The two month column on Exhibit 1.

Although deemed a coincidence by his doctor when I paged him, I was certain that the vaccine had caused his screaming, seizure, blood in stool, and catatonic state for the following two days.

But I was told it was a coincidence, was given CDC fact sheets on the diseases and the importance of vaccinations, and urged to continue his shots.

So how does a Mom like me educate herself on vaccines?

First of all, like I said, it is a very personal issue. I believe that each of us must make our own decision on what is safe and effective for promoting our children's' health. The state should not decide for us.

But in case you are wondering how I educated myself, I began with VAERS database. This database – the Vaccine Adverse Event Reporting System - captures only a small percentage of actual reactions, and the data were compelling enough to me to look further and to ask more questions.

While researching, I discovered that vaccine manufacturers do not have any incentive whatsoever to actually make vaccines safe. National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34) was enacted in the United States to reduce the potential financial liability of vaccine makers due to vaccine injury claims. The legislation came after manufacturers said there was not enough money in vaccines (and by the way), that has changed drastically today.

This fact alone was enough for me to call into question why we are wholeheartedly supporting our vaccination campaigns when there is no incentive for the companies who produce them to care about unwanted side effects. Unless a corporation is a B Corporation, their motive will always be profit first.

Pandora's Box

This bill, in my opinion, is pandora's box. Last year's U.S. Supreme Court decision giving drug companies total liability protection for injuries and deaths caused by government mandated vaccines is outrageous, and further calls into question why anyone would blindly trust the package inserts. The vaccine industry is growing, with estimates reaching $20 billion. And there is Zero liability. Zero incentive to change our course.

This bill comes at a time when, in the words of Robert F. Kennedy, Jr., " Serious scientists (except those tied to the vaccine industry) no longer debate whether vaccine-autism research should be done, but rather how it should be done, and by whom." See ***Exhibit 2***, The Pace Environmental Law Review, which speaks to Unanswered questions from the vaccine Injury Compensation Program.

Not only does this bill it tread on the rights of Vermonters, but it will I do nothing to change the vaccinations rates in Vermont. This is why:

1. Those using the philosophical objection (like me) have already done their (my) homework. They (I) have looked at every VAERS report (http://vaers.hhs.gov/data/data) , every published, peer

reviewed study available. Any amount of "education" is not going to change their (my) mind.

2. Despite media reports saying we are one of the lowest states in the country, Vermont ranks 27th out of 50 states and has a higher overall vaccination rate in the 4:3:1:3:3:1:4 series than the following states: AL, CA, CO, DE, GA, ID, KY, ME, MD, MO, MT, NV, NJ, NM, NY, OK, OR, RI, SD, UT, WV, WY and has a higher overall rate than the following states that DO NOT have a philosophical exemption: AL, DE, GA, KY, MD, MT, NV, NJ, NY, RI, SD, WY (see ***Exhibit 3***, the table with all the little bitty numbers).

3. If indeed raising vaccination rates is the issue here, then it would make a lot more sense to focus on the 10% of children simply failing to obtain the 4th dose of DTaP and the 8% of children failing to get the 4th dose of PCV rather than eliminating the philosophical exemption all together for the small percentage of families who use it. Just helping current vaccinators to finish the schedule on time would dramatically increase overall vaccination rates. Again – look at the numbers.

I encourage all of you, for Vermont, state of Freedom and Unity, to continue to let parents decide for themselves what is safe and effective.

Will the senate let fear mongering shape our reality and remove the philosophical exemption? Do we really want this for Vermont?

We do not have to do this just because other states have caved (CA, WA, VA). In fact the Virginia House just repealed the HPV mandate they had placed on girls in their state. Virginia Delegate Kathy Byron, R-Campbell was the sponsor of the bill to repeal the law, and said the immunization decision "should be the sole prerogative of families and their physicians." Byron urged her colleagues to reject the amendment. "It is not our responsibility to become an advertising agency for the drug companies," she said.

Bravo for Virginia. I hope that Vermont will take the courage it needs to make the right choice for Vermonters, by keeping the philosophical exemption and rejecting this bill.

American Academy of Pediatrics
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Vermont Chapter

VTAFP

Most Frequently Asked Questions about Vaccines

Q. If the diseases that vaccines prevent are now rare, why should my child still get vaccines?
A. Although several of the diseases that vaccines prevent have been dramatically reduced or eliminated, vaccines are still necessary to prevent common infections, to prevent infections that could easily reemerge, and to prevent infections that are common in other parts of the world. Although some diseases have been completely eliminated (polio) or virtually eliminated (diphtheria) from this country, they still occur commonly in other parts of the world. Because there is a high rate of international travel, **outbreaks of these diseases are only a plane ride away.**

Q. Are vaccines safe?
A. Because vaccines are given to people who are not sick, they are held to the highest standards of safety. As a result, they are among the safest things we put into our bodies. Although all vaccines have some side effects, most are mild (such as fever, or tenderness and swelling where the shot is given). Some side effects from vaccines may (rarely) be more severe. For example, the pertussis vaccine is a very rare cause of persistent inconsolable crying, high fever or seizures with fever. Although these reactions do not cause permanent harm to the child, they can be quite frightening. Decreasing rates of pertussis vaccination in other countries has led to a tenfold increase in hospitalizations and deaths. When you consider the risk of vaccines and the risk of diseases, vaccines are the safer choice.

Q. What ingredients are in vaccines?
A. All vaccines contain antigens, substances that prompt the body to create the immune response needed to protect against infection. Some examples of antigens are: weakened live viruses, inactivated (or killed) viruses, and partial viruses and bacteria. Vaccines also contain other ingredients, which help make them safer and more effective; these include preservatives, adjuvants and additives. Example of additives include substances like gelatin and sucrose. **Vaccines do not include antifreeze (or its ingredient, ethylene glycol).**

The amount of each additive used in vaccines is very small. In fact, we are exposed to much higher levels of these chemicals in our everyday lives. In vaccines, these ingredients are used to make the vaccine safer and more effective. Each vaccine is tested many times to make sure it is safe and works. Taking ingredients out might affect the ability of the vaccine to protect a child.

Q. Do vaccines contain mercury?
A. Thimerosal, a mercury-based preservative, was removed from most childhood vaccines in 2001. It is still present in some influenza vaccines. Thimerosal is still used in the manufacture of some vaccines to prevent contamination. The thimerosal is removed at the end of the manufacturing process. In some cases, a tiny amount of thimerosal remains. The remaining amount is so small, that it is not possible for it to have any effect. Valid scientific studies have shown there is no link between thimerosal and autism. In fact, autism rates have actually increased since thimerosal was removed from childhood vaccines. The American Academy of Pediatrics (AAP), the American Medical Association (AMA), the CDC, and the Institute of Medicine (IOM) agree that science does not support a link between thimerosal in vaccines and autism. For the IOM report, go to: http://www.iom.edu/CMS/3793/4705/4717.aspx.

Q. Why aren't all vaccines 100% effective?
A. Vaccines are designed to generate an immune response that will protect the vaccinated individual during future exposures to the disease. Individual immune systems, however, are different enough that in some cases, a person's immune system will not generate an adequate response. As a result, he or she will not be effectively protected after immunization. That said, the effectiveness of most vaccines is high. After receiving the second dose of the MMR vaccine (measles, mumps and rubella) or the standalone measles vaccine, 99.7% of vaccinated individuals are immune to measles. The inactivated polio vaccine offers 99% effectiveness after three doses. The varicella (chickenpox) vaccine is between 85% and 90% effective in preventing all varicella infections, but 100% effective in preventing moderate and severe chicken pox.

Q. What is herd immunity? Is it real? Does it work?
A. Herd immunity, also known as community immunity, refers to the protection offered to everyone in a community by high vaccination rates. With enough people immunized against a given disease, it's difficult for the disease to gain a foothold in the community. This offers some protection to those who are unable to receive vaccinations—including newborns and individuals with chronic illnesses—by reducing the likelihood of an outbreak that could expose them to the disease.

Q. Is natural immunity better than vaccine-acquired immunity?
A. In some cases, natural immunity is longer-lasting than the immunity gained from vaccination. The risks of natural *infection*, however, outweigh the risks of immunization for every recommended vaccine. For example, wild measles infection causes encephalitis (inflammation of the brain) for one in 1,000 infected individuals. Overall, measles infection kills two of every 1,000 infected individuals. In contrast, the combination MMR (measles, mumps and rubella) vaccine results in a severe allergic reaction only once in every *million* vaccinated individuals, while preventing measles infection. The benefits of vaccine-acquired immunity extraordinarily outweigh the serious risks of natural infection. Additionally, the Hib (Haemophilus Influenzae Type b) and tetanus vaccines actually provide more effective immunity than natural infection.

Q. Isn't it true that better hygiene and nutrition were responsible for decreases in deaths and disease rates, rather than vaccines?
A. Improved hygiene and nutrition, among other factors, can certainly lower the incidence of some diseases. Data documenting the number of cases of a disease before and after the introduction of a vaccine, however, demonstrate that vaccines are overwhelmingly responsible for the largest drops in disease rates. Measles cases, for example, numbered anywhere from 300,000 to 800,000 a year in the United States between 1950 and 1963, when a newly licensed measles vaccine went into widespread use. By 1965, U.S. measles cases were beginning a dramatic drop. In 1968 about 22,000 cases were reported (a drop of 97.25% from the height of 800,000 cases in just three years); by 1998, the number of cases averaged about 100 per year or less. Perhaps the best evidence that vaccines, and not hygiene and nutrition, are responsible for the sharp drop in disease and death rates is chicken pox. If hygiene and nutrition alone were enough to prevent infectious diseases, chicken pox rates would have dropped long before the introduction of the varicella vaccine, which was not available until the mid-1990s. Instead, the number of chicken pox cases in the United States in the early 1990s, before the vaccine was introduced in 1995, was about four million a year. By 2004, the disease incidence had dropped by about 85%.

Q. Do children get too many shots?
A. Newborns commonly manage many challenges to their immune systems at the same time. Because some children could receive as many as 25 shots by the time they are 2 years old and as many as five shots in a single visit to the doctor, many parents wonder whether it is safe to give children so many vaccines. Although the mother's womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune systems from the moment of birth. By quickly making immune responses to these bacteria, babies keep them from invading the bloodstream and causing serious diseases. The vaccines given in the first two years of life are a raindrop in the ocean of what an infant's immune system successfully encounters and manages every day.

Q. Do vaccines cause autism?
A. This possibility was publicized after a 1998 paper by a British physician who claimed to have found evidence that the MMR (measles, mumps and rubella) vaccine was linked to autism. The potential link has been thoroughly explored; study after study has found no such link, and the original 1998 study has been formally withdrawn by the *Lancet*, which had originally published it. Studies were also done regarding the possibility of a link between the preservative thimerosal, which is used in some vaccines, and autism; again, no such link was found.

Q. Can I delay or skip vaccines?
A. It is not a good idea to skip or delay vaccines, as this will leave your child vulnerable to diseases for a longer time. Children are most vulnerable to complications from disease in their early years of life, when vaccines provide protection, and some vaccines produce a better immune response at particular ages. Parents should follow the schedule provided by the U.S. Centers for Disease Control and Prevention, the American Academy of Pediatrics and the American Academy of Family Physicians, which is designed by experts to ensure maximum protection and safety for children at various ages.

Answers extracted from the following resources: The American American Academy of Pediatrics Q& A about Vaccine Ingredients - http://www.aap.org/en-us/my-aap/advocacy/workingwiththemedia/speaking-tips/Documents/vaccineingredients.pdf; The Childrens Hospital of Philadelphia Facts about Childhood Vaccines - http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/vaccines-fact.pdf; The History of Vaccines – A project of the College of Physicians of Philadelphia - http://www.historyofvaccines.org/content/articles/top-20-questions-about-vaccination

American Academy of Pediatrics
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Facts for Parents About Vaccine Safety

Why are vaccines important?

Immunizations protect children. Vaccine-preventable diseases can have dangerous consequences, including seizures, brain damage, blindness and even death. Because of the success of the national immunization program, many young parents today have never seen a case of one of these illnesses, but measles, meningitis, chickenpox, pertussis and other diseases exist in the world and would re-emerge here if immunization rates fell. For example, recent outbreaks of measles in the U.S. were traced to unvaccinated children who became infected while traveling in Europe. Likewise, it would only take one case of polio from another country to bring the disease back to the U.S. if children are not protected by vaccination.

Are vaccines safe?

Yes. Today's vaccines are safer than any in history. Vaccines contain antigens, which are either live but very weakened viruses, inactivated viruses, or small parts of bacteria or viruses that prompt the body to produce protective antibodies without causing the disease. Even though children receive more vaccines now, the total number of antigens is less because today's vaccines are more refined than older versions. At a very young age, children's immune systems are equipped to respond to many antigens at the same time, including those in vaccines as well as the ones they encounter in their daily activities such as eating, breathing and playing.

In addition to antigens, vaccines contain ingredients to prevent contamination and improve effectiveness. These ingredients have been found to be safe in humans in the quantities given in vaccines, which is much less than children are exposed to in their environment, food and water. Valid scientific studies have shown there is no link between autism and thimerosal, a mercury-based preservative once used in several vaccines (and still used in some flu vaccine). However, since thimerosal was removed from childhood vaccines in 2001, autism rates have actually increased, supplying further evidence that thimerosal does not cause autism.

Before a vaccine is licensed, it is studied in thousands of children and in combination with other vaccines. After licensure, the federal government continues to monitor a vaccine's safety. This continuous monitoring ensures researchers will uncover any rare side effects, even if they affect only a small number of children. For example, a rotavirus vaccine was withdrawn in 1999 after it was linked to intestinal blockages in about 100 children. This vaccine was replaced by a new and safer product. Today's recommended vaccines have been shown to be safe and effective for millions of children.

Can I delay or skip vaccines?

It is not a good idea to skip or delay vaccines, as this will leave your child vulnerable to diseases for a longer time. Children are most vulnerable to complications from disease in their early years of life, when vaccines provide protection, and some vaccines produce a better immune response at particular ages. Parents should follow the schedule provided by the U.S. Centers for Disease Control and Prevention, the American Academy of Pediatrics and the American Academy of Family Physicians, which is designed by experts to ensure maximum protection and safety for children at various ages. This schedule allows for some flexibility to delay certain shots when advised by a child's pediatrician due to illness, certain chronic conditions or other medical reasons. Parents should discuss any concerns with their child's pediatrician.

More information is available at www.aap.org/immunization and www.cdc.gov/vaccines.

June 2008

Q&A

The Facts About Childhood Vaccines

Volume 6, Spring 2009

The Children's Hospital of Philadelphia®

VACCINE EDUCATION CENTER

Q. How can parents sort out conflicting information about vaccines?

A. Decisions about vaccine safety must be based on well-controlled scientific studies.

Parents are often confronted with "scientific" information found on television, on the Internet, in magazines and in books that conflicts with information provided by healthcare professionals. But few parents have the background in microbiology, immunology, epidemiology and statistics to separate good scientific studies from poor studies. Parents and physicians benefit from the expert guidance of specialists with experience and training in these disciplines.

Committees of these experts are composed of scientists, clinicians and other caregivers who are as passionately devoted to our children's health as they are to their own children's health. They serve the Centers for Disease Control and Prevention (www.cdc.gov/vaccines), the American Academy of Pediatrics (www.aap.org) and the Infectious Diseases Society of America (www.nnii.org), among other groups. These organizations provide excellent information to parents and healthcare professionals through their Web sites. Their task is to determine whether scientific studies are carefully performed, published in reputable journals and, most importantly, reproducible. Information that fails to meet these standards is viewed as unreliable.

When it comes to issues of vaccine safety, these groups have served us well. They were the first to figure out that intestinal blockage was a rare consequence of the first rotavirus vaccine, and the vaccine was quickly discontinued. And they recommended a change from the oral polio vaccine, which was a rare cause of paralysis, to the polio shot when it was clear that the risks of the oral polio vaccine outweighed its benefits.

These groups have also investigated possible relationships between vaccines and asthma, diabetes, multiple sclerosis, SIDS and autism. No studies have reliably established a causal link between vaccines and these diseases — if they did, the questioned vaccines would be withdrawn from use.

Q. Do vaccines contain additives?

A. Many vaccines contain trace quantities of antibiotics or stabilizers.

Antibiotics are used during the manufacture of vaccines to prevent inadvertent contamination with bacteria or fungi. Trace quantities of antibiotics are present in some vaccines. However, the antibiotics contained in vaccines (neomycin, streptomycin or polymyxin B) are not those commonly given to children. Therefore, children with allergies to antibiotics such as penicillin, amoxicillin, sulfa, or cephalosporins can still get vaccines.

Gelatin is used to stabilize live viral vaccines and is also contained in many food products. People with known allergies to gelatin contained in foods may have severe allergic reactions to the gelatin contained in vaccines. However, this reaction is extremely rare.

Offit PA, Jew RK. Addressing parents' concerns: Do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics* 2003;112:1394-1401.

American Academy of Pediatrics. In Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases.* 26th ed. Elk Grove Village, IL.

Q. If the diseases that vaccines prevent are now rare, why should my child still get vaccines?

A. Although several of the diseases that vaccines prevent have been dramatically reduced or eliminated, vaccines are still necessary:

- ***to prevent common infections***

Some diseases are so common in this country that a choice not to get a vaccine is a choice to get infected. For example, choosing not to get the pertussis (whooping cough) vaccine is a choice to risk a serious and occasionally fatal infection.

- ***to prevent infections that could easily reemerge***

Some diseases in this country continue to occur at very low levels (for example, measles, mumps and *Haemophilus influenzae* type b, or Hib). If immunization rates in our schools or communities are low, outbreaks of these diseases are likely to occur. This is exactly what happened in the late 1980s and early 1990s when thousands of children were hospitalized with measles and more than 120 died. Children were much more likely to catch measles if they weren't vaccinated.

- ***to prevent infections that are common in other parts of the world***

Although some diseases have been completely eliminated (polio) or virtually eliminated (diphtheria) from this country, they still occur commonly in other parts of the world. Children are commonly paralyzed by polio in India or killed by diphtheria in Russia. Because there is a high rate of international travel, outbreaks of these diseases are only a plane ride away.

Atkinson W, et al. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 9th Edition. Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services, 2006.

Q. Are vaccines safe?

A. Because vaccines are given to people who are not sick, they are held to the highest standards of safety. As a result, they are among the safest things we put into our bodies.

How does one define the word safe? If safe is defined as "free from any negative effects," then vaccines aren't 100 percent safe. All vaccines have possible side effects. Most side effects are mild, such as fever, or tenderness and swelling where the shot is given. But some side effects from vaccines can be severe. For example, the pertussis vaccine is a very rare cause of persistent inconsolable crying, high fever or seizures with fever. Although these reactions do not cause permanent harm to the child, they can be quite frightening.

If vaccines cause side effects, wouldn't it be "safer" to just avoid them? Unfortunately, choosing to avoid vaccines is not a risk-free choice — it is a choice to take a different and much more serious risk. Discontinuing the pertussis vaccine in countries like Japan and England led to a tenfold increase in hospitalizations and deaths from pertussis. Recently, a decline in the number of children receiving measles vaccine in the United Kingdom led to an increase in measles hospitalizations and deaths.

When you consider the risk of vaccines and the risk of diseases, vaccines are the safer choice.

Plotkin S, et al. *Vaccines.* 4th Edition, W.B. Saunders and Co., 2004.

more ▸

Q. Do children get too many shots?

A. Newborns commonly manage many challenges to their immune systems at the same time.

Because some children could receive as many as 25 shots by the time they are 2 years old and as many as five shots in a single visit to the doctor, many parents wonder whether it is safe to give children so many vaccines.

Although the mother's womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune systems. From the moment of birth, thousands of different bacteria start to live on the surface of the intestines. By quickly making immune responses to these bacteria, babies keep them from invading the bloodstream and causing serious diseases.

In fact, babies are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in the bodies. Therefore, vaccines given in the first two years of life are a raindrop in the ocean of what an infant's immune system successfully encounters and manages every day.

Offit PA, et al. Addressing parents' concerns: Do vaccines weaken or overwhelm the infant's immune system? *Pediatrics.* 2002,109:124-129.

Q. Is the amount of aluminum in vaccines safe?

A. Yes. All of us have aluminum in our bodies and most of us are able to process it effectively. The two main groups of people who cannot process aluminum effectively are severely premature infants who receive large quantities of aluminum in intravenous fluids and people who have long-term kidney failure and receive large quantities of aluminum, primarily in antacids. In both cases the kidneys are not working properly or at all *and* the people are exposed to large quantities of aluminum over a long period of time.

The amount of aluminum in vaccines given during the first six months of life is about 4 milligrams, or four-thousandths of a gram. A gram is about one-fifth of a teaspoon of water. In comparison, breast milk ingested during this period will contain about 10 milligrams of aluminum and infant formulas will contain about 40 milligrams. Soy-based formulas contain about 120 milligrams of aluminum.

Finally, when studies were performed to look at the amount of aluminum injected in vaccines, the levels of aluminum in blood did not detectably change. This indicates that the quantity of aluminum in vaccines is minimal as compared with the quantities already found in the blood.

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Q. Do vaccines cause autism?

A. Carefully performed studies clearly disprove the notion that vaccines cause autism.

Because the signs of autism may appear in the second year of life, at around the same time children receive certain vaccines, and because the cause of autism is unknown, some parents wonder whether vaccines might be at fault. These concerns have focused on two hypotheses — the measles-mumps-rubella (MMR) vaccine, or thimerosal, an ethylmercury-containing preservative used in vaccines, was the cause of autism.

The vast weight of medical and scientific evidence now strongly refutes both notions. Multiple studies of both MMR and thimerosal have found that vaccines do not cause autism. These studies included hundreds of thousands of children, occurred in multiple countries, were conducted by multiple investigators and were well controlled.

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Q. What is the harm of separating, spacing out or withholding some vaccines?

A. Although the vaccine schedule can look intimidating, it is based upon the best scientific information available and is better tested for safety than any alternative schedules.

Experts review studies designed to determine whether the changes are safe in the context of the existing schedule. These are called concomitant-use studies.

Separating, spacing out or withholding vaccines causes concern because infants will be susceptible to diseases for longer periods of time. When a child should receive a vaccine is determined by balancing when the recipient is at highest risk of contracting the disease and when the vaccine will generate the best immune response.

Finally, changing the vaccine schedule requires additional doctor's visits. Research measuring cortisol, a hormone associated with stress, has determined that children do not experience more stress when receiving two shots as compared with one shot. Therefore, an increased number of visits for individual shots will mean more stressful situations for the child. In addition, there is an increased potential for administration errors, more time and travel needed for appointments, and potentially increased costs.

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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

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Clear Answers & Smart Advice About Your Baby's Shots

By Ari Brown, MD, FAAP

Dr. Brown received her medical degree from Baylor College of Medicine in Houston, Texas; she did her pediatric residency at Harvard Medical School/Boston Children's Hospital. In private practice since 1995, Dr. Brown is perhaps best known as the coauthor of ***Baby 411: Clear Answers & Smart Advice for Your Baby's First Year*** (Windsor Peak Press).

In response to the recent media attention given to vaccines, autism, and other controversies concerning vaccines, the Immunization Action Coalition (IAC) has reprinted a special excerpt from *Baby 411* that answers these questions and more. IAC is grateful to Dr. Brown for these clear answers and smart advice, but mostly, we are grateful for her continued advocacy for safe and effective vaccines.

Vaccines. Autism. Controversy. As a new parent (or parent-to-be), it's hard not to hear the great debate in parenting circles these days—do vaccines cause autism? If not, what causes autism? Why is it on the rise? And what is autism anyway?

Let's start at the beginning—just what is autism?

What is autism?

Autism Spectrum Disorder (ASD) is really a collection of several disorders that have three abnormal areas in common: social skills, communication skills, and repetitive or obsessive traits. There's a broad range from mildly to severely affected. Specialists use the terms ASD and Pervasive Developmental Disorders (PDD) interchangeably. And, to get even more confusing, Asperger's syndrome, and "pervasive developmental disorder, not otherwise specified" (PDD-NOS) are other categories that fall under the ASD heading. Here is a brief explanation of each:

Autism Spectrum Disorder (ASD) or Pervasive Developmental Disorder (PDD): These terms describe the entire group of conditions that include autism, Asperger's Syndrome, and PDD-NOS:

- **Autism:** These children are the most severely impaired. They have little or no social and communication skills and have repetitive, obsessive behaviors.
- **Asperger's Syndrome:** These children have normal intelligence and language development but have trouble reading social cues and making conversation. Asperger's kids often obsess about certain interests.
- **PDD-NOS** (Pervasive Developmental Disorder—Not Otherwise Specified) is the default diagnosis for a child who has problems with social and communication skills, but does not fit into either of the above categories.

Autism affects one in 150 children. It is four times more common in males, and seems to run in families.

I've heard autism is on the rise. Why?

The first question we have to ask is, do we really have an epidemic or are more children just being diagnosed? Is it better detection due to better awareness? Are we displacing one diagnosis for another? Here are some explanations for the large rise in autism:

1. **Displacing one diagnosis for another.** In previous generations, many children were diagnosed with mental retardation, schizophrenia, or some other psychiatric disorder. Today, many of these same kids are diagnosed with severe autism.

   For example, in 1996, 1 in 63 kids were diagnosed with mental retardation (measured by an IQ score of under 70). Yet, in 2000, that number DROPPED to 1 in 83. Why? Were there suddenly much fewer kids with mental retardation? No, many of these kids are now diagnosed with autism instead of mental retardation.[1] In other words, autistic kids were there in the 80's and 90's—we just didn't call them autistic.

   In 1991, the Individuals with Disabilities Education Act (IDEA) required children with developmental disabilities to receive school services and be integrated into a mainstream classroom setting as much as possible. Autism was added as a new diagnosis for which a child could be eligible to receive educational services. In 1993, two years after this code was added, the Department of Education reported a 23% rise in autism. Prior to the coding change, kids with autism were often labeled with non-specific developmental delay, brain dysfunction, or mental retardation.

2. **Changing criteria, broader diagnosis.** The definition of autism has changed over the years. The Diagnostic and Statistical Manual of Mental Disorders (DSM) is the authoritative bible for psychiatric disorders in the U.S. The first two editions never even listed autism as a disorder.

   Dr. Leo Kanner first diagnosed autism in the 1940's. Yet it was not until 1980 when psychologists recognized autism. That's when the DSM for the first time listed criteria for diagnosis of autism.

   The autism diagnosis broadened again in 1994 when several more disorders were officially added to the DSM: Pervasive Developmental Disorder (PDD), PDD-NOS (not otherwise specified), Asperger's Syndrome, Childhood Disintegrative Disorder, and Rett's Disorder.

   By expanding the definition of autism, suddenly many more kids were declared autistic. Case in point: looking at recent autism diagnoses, up to 75% of these kids are high-functioning children with PDD-NOS or Asperger's.

   Unfortunately, many states don't break out where kids are on the autism spectrum. California's autism rate is often cited in the media as example of the "autism epidemic"—yet California doesn't specify where kids are on the autism spectrum, so it's hard to get solid numbers.

   Not long ago, kids who were smart but socially awkward had no diagnosis. Today, those kids are often diagnosed with Asperger Syndrome.[2]

3. **Better awareness, better and earlier diagnosis.** Popular diagnoses rise and fall like skirt lengths. Think about it—ten years ago, had you ever heard of Restless Leg Syndrome?

continued

When it comes to autism, this newfound awareness is actually a positive step. More people—parents and doctors alike—are on the lookout for children with autism.

Making a diagnosis and starting therapy earlier in life improves kids' longterm outcomes. But it also looks like autism is on the rise. Why? Because kids were previously diagnosed with autism after age five or six. Today, kids are diagnosed as early as 18 months of age. This adds many more kids to the rolls . . . but is autism really increasing? Or is there just an earlier diagnosis?

4. **Why does the U.S. have so many autism cases?** Autism is not just an American disease—it happens worldwide. But why do the U.S. and United Kingdom have such high autism rates? That's because the U.S. and U.K. have done the lion's share of research and studies into autism.

   Other countries are just starting to look into autism. For instance, in South Korea, kids are diagnosed with Reactive Attachment Disorder (RAD) . . which is really what we call Autism Spectrum Disorder (ASD) here in the U.S. We suspect that South Korea will report an alarming rise in autism when they figure out their RAD kids are the same as our ASD kids.

   And counting autistic kids is a relatively recent phenomenon. Before recent legislation led to schools labeling more kids as autistic, researchers just looked at either medical or school records to determine autism rates. This was imprecise to say the least.[3]

5. **Prevalence vs. Incidence.** If you've ever taken a statistics class (or tried hard to forget anything you learned if you did), here is a little review. Most of what we know about autism rates are based on prevalence studies: these are a sampling of a population at one point in time used to estimate overall rates. By contrast, incidence studies identify the ACTUAL number of autism cases over a period of time. The only way to know if autism is really an epidemic is to see a rise in the incidence of autism.

   Unfortunately, there are very few incidence studies of autism. That's because it is extremely difficult to do this research. Only one incidence study on autism is available—that 2005 report found that rates of PDD in the 90's were unchanged. So even though PREVALANCE studies seem to show autism is increasing, the incidence proof is lacking.[4]

6. **Social acceptance.** We've come a long way since autism was first identified as a disorder. Orignally, experts thought autism was caused by poor parenting—namely, the mother. These "Refrigerator Moms" were blamed for rejecting their kids, causing the kids to have social problems.

   Of course, this was WRONG. What we've learned over the past 70 years is that autism is not the mom's fault. But in the old days, no mother wanted their kid labeled autistic since that would imply HER guilt.

   Today, we realize it is not mom's fault—and thus parents are more willing to accept an ASD diagnosis. And the diagnosis now allows for special education services, which many parents realize can help their child.

7. **Over or misdiagnosis?** There is so much awareness now of Autism Spectrum Disorders, that perhaps clinicians are overdiagnosing it. One reputable study suggests that kids who actually have anxiety disorders, obsessive compulsive disorders, and personality disorders may be misdiagnosed now with ASD.[5]

   These are possible explanations for the "autism epidemic"—but we don't have all the answers yet. The bottom line: in the 1980's, one in 10,000 kids were diagnosed with autism. Today, it's one in 150. The U.S. is not the only country seeing this trend. Australia, Canada, Denmark, Finland, Iceland, Japan, and Sweden also report a disconcerting rise.

Okay, so what causes autism?

The million dollar question. There appear to be four chief suspects:

1. **Genetics.** We know genetics plays a role. Studying twins is an obvious way to detect genetic disorders. If one identical twin has autism, up to 96% of the time, so will the other twin. And siblings of ASD kids have a 5% risk of having an autistic disorder.[6] To date, the exact gene has not been identified, but it may reside on the X chromosome, which may explain the prevalence of autism in boys.[7] In fact, there is a genetic syndrome (called Fragile X) that is one known cause of autism.

   In 2008, researchers identified a specific gene in some kids with autism. This gene is involved in controlling brain cell communication.[8] It appears that some kind of mutation in this gene causes a risk of autism within families.

   Other researchers have found abnormalities on chromosomes of autistic kids. Hence it appears that autism is caused by several different genetic defects, although researchers haven't quite figured out the puzzle yet.[9]

   One study has shown that dads over the age of 40 have SIX times greater risk of having a child with an autistic disorder than dads who are younger than 30.[10] Hence, autism has eerie echoes of Down Syndrome, a genetic defect that is more common when a mother has "advanced maternal age" (over age 35).

   All of these studies show that genetic defects are a strong suspect in autism.

2. **Abnormal brain growth.** Although the cause is unknown, autistic children have problems with brain growth. Babies are born with immature brains that grow rapidly and make nerve connections called synapses...like an information superhighway. In the normally growing brain, some branches of this superhighway get "pruned." In the autistic child's brain, the pruning process is defective. This may explain why babies with autism have abnormally rapid head growth under one year of age. Boys with ASD seem to have higher levels of hormones (insulin-like growth factors), which may contribute to the larger head size, weight, and body mass index.[11]

3. **Environmental trigger.** Is there some environmental exposure that sets off abnormal brain development in a genetically predisposed baby? Maybe. And that exposure may happen at or shortly after conception—before a mother even knows she is pregnant. There is a critical period of fetal brain development that occurs at 20-24 days after conception where the brain is most sensitive to injury.

   Here are just a few theories that scientists are exploring as a cause for autism: flu exposure during pregnancy, and folic acid levels in Dad-to-be's sperm (possibly a too-high level can lead to problems). Studies done by the Environmental Working Group have found about 280 environmental toxins in umbilical cord blood—could one of these be a trigger?

   There is also a growing body of evidence that newborns who are later diagnosed with ASD already have abnormal levels of certain proteins in their brains. So, having an environmental trigger in the womb during a critical period of brain development seems a plausible explanation for autism.

   What about vaccines? There has been much talk about this theory specifically that trace amounts of mercury used as a preservative in many vaccines prior to 2001 caused a spike in autism. We discussed this issue in depth in *Baby 411,* but just to sum up: the scientific evidence does not support this theory. Research during the past ten years

has taken a long hard look at vaccines and found conclusive evidence that vaccine exposure is NOT the turn-on switch for autism.[12] And no, despite what you might read online from fringe groups or plaintiff lawyers, there is no conspiracy among pharmaceutical companies to inflict autism on unsuspecting children.

The U.S. Centers for Disease Control and Prevention (CDC) has long-term studies underway to examine vaccines and autism. The most recent results, published in the *New England Journal of Medicine,* showed that the mercury preservative previously present in vaccines had no significant effect on either intelligence or developmental delays in kids ages seven to 10. The results of the CDC's study on mercury preservative and autism specifically will be published after this booklet goes to print. Stay tuned on our website for updates.

4. **Premature birth.** A recent study in the journal *Pediatrics* found that premature babies born at 25 to 26 weeks gestation have a 25% chance of developing an autism spectrum disorder.

BOTTOM LINE: Researchers don't know what causes autism, although the above factors provide clues. The goal is to find a way to PREVENT autism . . . but we aren't there yet.

Is it possible that autism is actually mercury poisoning?

No. Mercury poisoning, also known as Mad Hatter's Disease, is very different from autism. Symptoms of mercury poisoning include excessive sweating, tremors and kidney problems. Sufferers also talk and walk like they have had a stroke.

How do we know this? The information known about mercury poisoning comes from unfortunate communities that have experienced it. There is a large amount of data from the Faroe Islands, near Iceland. The people there would eat whale blubber contaminated with toxic levels of methyl mercury and polychlorinated biphenyls (PCBs). Children, especially those exposed as fetuses during their mother's pregnancy, seemed to have lower scores on memory, attention, and language tests than their unexposed peers.

Here's the rub: despite all those problems, these children with mercury poisoning were NOT diagnosed with autism.

Another key point: mercury preservative was taken out of required vaccines SEVEN years ago. But autism rates are still going up.

Did the mercury in vaccines cause autism?

No. Here is the scientific evidence:

- The Institute of Medicine spent four years studying this issue. Their conclusion, issued in 2004: mercury preservatives in vaccines did NOT cause autism . . . and the Institute said it was time to move on to look at other possible causes. Several other leading medical organizations (both nationally and internationally) agree with this conclusion.
- Mercury preservative (thimerosal) was removed from vaccines commonly given to infants and young children in the U.S. in 2001, but the rates of children being diagnosed with autism are still skyrocketing. A survey of autism rates in California in 2008 confirms that mercury is out and autism rates are still going up.[13] If thimerosal was the cause of autism, and it was taken out SEVEN years ago, autism rates should be going down by now. That's because autism spectrum disorders are usually diagnosed by three years of age.
- Mercury preservatives were removed from vaccines in Denmark in 1992. Canada and the European Union have followed suit. Their autism diagnosis rates are still going up, too.

  Mad Hatter's Disease (mercury poisoning) and autism are very different disorders, as discussed above.
- A study of 100,000 kids in England compared those receiving mercury-containing vaccines to those who did not. The ones who had the mercury-free shots had HIGHER rates of autism.
- A study in 2007 showed that children between seven and ten years of age who got those mercury containing vaccines (before 2001) had no significant differences in tests of attention and processing information.[14] Although the study did not look specifically at autism, it showed that mercury preservatives did not make much of an impact on brain functions in general.

Do vaccines still contain mercury? What about the flu vaccine?

In 2001, the FDA required manufacturers to discontinue using mercury preservative for ALL routine childhood vaccines. Period.

Many vaccines, like that for measles, mumps and rubella (MMR), have NEVER contained mercury preservatives. Nor is mercury used in the production process for MMR. However, there are four vaccines on the market that still use mercury preservative in the manufacturing process—the mercury is then REMOVED from the final vaccine.

Because the flu vaccine is reformulated each year for the upcoming season, manufacturers need to move as efficiently as possible to produce large quantities of vaccine. The best way to do this is to produce vaccine in multi-dose vials, which requires a preservative. There are, however, single-dose preparations that are FREE of mercury preservatives that can be given to young children and pregnant women, if available.

Let's do a reality check here: a tuna sandwich has FIVE TIMES more mercury than one dose of flu vaccine.

As a doctor, I am much more concerned about mercury exposure in the environment—particularly in food (like that tuna fish sandwich). So if you are worried about mercury exposure, consider this: there's mercury in breast milk.

A baby gets 25 times more mercury by breastfeeding for six months than in a single dose of flu vaccine. Breast milk contains between 1.4 and 1.7 micrograms of methyl mercury per liter. If you assume that a baby is breast-fed exclusively up until six months of age, that baby will consume about 360 micrograms of methyl mercury. That's twice the amount of mercury that was ever contained in vaccines and 25 times the quantity of mercury contained in the influenza vaccine.

A quick chemistry lesson: certain compounds have completely different properties even though they have similar sounding names. For instance, there are TWO types of mercury: methyl mercury and ethyl mercury. The type of mercury that has raised health concerns is methyl mercury. Methyl mercury is a small molecule that can get into the brain and takes almost TWO MONTHS to break down. High concentrations of methyl mercury can be found in tuna, swordfish and shark from contaminated waters.

Now, let's contrast that with ETHYL mercury, which is/was the type of mercury used in vaccine preservatives. Ethyl mercury (thimerosal is an example) is rapidly eliminated from the body within a WEEK. Compared to methyl mercury, ethyl mercury is a much larger molecule that cannot enter the brain.

Ideally, it would be nice to remove ALL mercury preservatives from flu vaccines—so we could put this controversy to rest. The problem: at this time, the only way to manufacture the huge quantity of flu vaccine needed each year requires using mercury preservatives. Hopefully, vaccine makers will figure out a way to eliminate mercury from all vaccines in the future—so any concerns can finally be put to rest.

What do you think of delaying vaccines or using an alternative vaccination schedule?

The CDC publishes a recommended vaccine schedule for all children

in the U.S.—this schedule wasn't created from thin air . . . doctors, scientists and researchers work together to decide what is the best time to give shots. The goal: protect as many babies as soon as possible from deadly disease.

Now, one of the popular myths about autism is that somehow kids are getting "too many shots, too soon." Despite the scientific evidence that shows vaccines do NOT cause autism, some parents think that if they space out their kids' vaccines in an "alternative schedule" this is somehow safer.

Adding to this notion are blogs, books, and web sites that promote alternative vaccine schedules, delaying critical shots months or years after a child can safely receive them.

Here's a nasty little truth about alternative vaccination schedules: they are all fantasy. There is absolutely no research that says delaying certain shots is safer. Doctors who promote these schedules are simply guessing when to give which shots.

What we know for certain is that delaying your child's shots is playing Russian Roulette. The simple truth is you are leaving your child unprotected. Who knows what disease (preventable from a simple vaccine) will crop up next? Deadly diseases like measles are only a plane flight away.

Also: spreading out vaccinations creates new challenges. Live vaccines must be given at least four weeks apart to mount an active immune response. Take the MMR (measles, mumps, and rubella) vaccine—your child could get one combo shot and take care of all three deadly diseases at once. If you get three separate shots, however, it would take at least three months (because each is a live vaccine). That leaves kids unprotected until the series is completed.

When families demand a spaced out vaccination schedule, this is what I tell them as their doctor: "At the end of the day, I just want your child vaccinated. If you want to give two shots today and two next week, that's okay. Just come back. And promise me you will do it in a timely manner (that means you return in weeks, not months or years, to finish vaccination)." The goal: make sure the child is protected.

One important point to remember: despite all the media attention to this subject, very few parents actually choose to delay or opt out of vaccinations.

Are vaccines really necessary?

Yes. As a doctor, I am greatly worried when parents decide to delay or not to vaccinate their child. That's because vaccine-preventable diseases are real.

I have watched a child die from a vaccine-preventable disease while I helplessly stood by. I've cared for several babies gasping for breath with whooping cough. These diseases kill children. Respect them. Last year alone vaccines prevented 14 million infections and 33,000 deaths in the U.S.

Our grandparents remember diseases like polio. And how folks lined up to get vaccinated. Yet, you've probably never even heard of anyone with polio today. The great irony of vaccine success is that parents today are unfamiliar with the diseases they prevent.

In the past 10 years, I have seen two forms of bacterial meningitis basically disappear, thanks to vaccines. Before the HIB (*Haemophilus influenzae* type b) vaccine was developed, there were about 20,000 U.S. children a year who suffered or died from this infection. Now there are less than 200 cases per year. Before the pneumococcal conjugate vaccine, which protects against streptococcal meningitis, 17,000 American children per year had invasive infections with strep. And, about 200 kids died of this each year. Since vaccination, serious infections have been reduced by 90%. That's pretty amazing.

And no, you can't just let everyone else vaccinate their kids—and let them protect your un-vaccinated child.

Just look at the recent measles outbreak in 2008 in San Diego. It all started with a child, who was unvaccinated by parent choice. He returned from a trip to Switzerland with measles. He went on to infect TEN other unvaccinated children—his siblings, school friends, and three babies who were too young to be vaccinated who were exposed to that child in a doctor's waiting room. Of the 11 cases, one baby was hospitalized.

And this outbreak may be a trend. During the period January through July of 2008, the highest year-to-date cases of measles were reported in the U.S. since 1996: 131 cases from 15 states and the District of Columbia. Over 90% were unvaccinated or had unknown vaccination status and two-thirds of these cases that were eligible for vaccination were not vaccinated because of philosophical or religious beliefs. There were also 16 babies who were too young to be vaccinated. Babies, who are the most vulnerable to serious infection, do rely on other vaccinated children in the community to protect them when they are not old enough to be immunized.

So, when people argue that kids get too many shots today, I ask them if they'd rather their child get meningitis. And what about vaccines in the pipeline? If we've already got too many shots, would you decide to skip a future vaccine to prevent HIV? Probably not. That's because you know that vaccine might be the one that saves your child's life.

Didn't the government recently concede that vaccines caused autism?

As you may have heard on the news, the government recently decided to compensate a child whose autism was allegedly triggered by a vaccine. Here's the background behind the headline:

The Vaccine Injury Compensation Program has been holding special hearings called the Omnibus Autism Proceedings. This "Vaccine Court" is looking at allegations that 4900 children developed autism from vaccines. The court is first looking at nine cases to form opinions about the evidence.

One child, Hannah Poling, was awarded a monetary settlement. Hannah was born with a rare genetic disorder (mitochondrial disorder, which is a dysfunction in basic cell metabolism). This is the equivalent of being born with an undetected heart defect—a ticking time bomb that could go off at any time.

For rare kids like Hannah, any stress could have caused her to develop autism. In fact, having a vaccine-preventable disease like the flu or chickenpox could have far worse health consequences—a disease like that could have killed her. Although she was not diagnosed prior to being vaccinated, experts recommend that even children with known mitochondrial disorders still be vaccinated.

So even though the headlines screamed that (in this case) a vaccine caused autism, the facts of the case show this isn't true. Hannah's underlying disease caused her deterioration and autism. The case was settled and determined that it did not represent a test case for the 4899 other children.

Experts on mitochondrial disorders do NOT think this disease is the "smoking gun" that triggers autism. That's because many folks have similar dysfunctional cells but never become autistic.

And there is no simple test for mitochondrial disorders. Instead, you must do a difficult and painful muscle biopsy and a spinal tap. As a result, testing all kids for mitochondrial disorders is not necessary, ethical or practical. And even if your child is diagnosed with a mitochondrial disorder, the recommendation is still to vaccinate.

Does the MMR vaccine cause autism?

One small study of only eight patients in 1998 led a British research

group to conclude that the combination MMR vaccine might cause autism.[15] But in March 2004, after questions were raised about the study, n of the 13 researchers of the study withdrew their claim of having found a possible connection between MMR and autism. They said, "In this paper, NO CAUSAL LINK was established between MMR vaccine and autism as the data were insufficient...now is the appropriate time that we should together formally retract the interpretation of the data suggesting a link."[16]

Numerous major studies (at least 17 so far) since 1998 also soundly refute this alleged link. The most prominent: the Institute of Medicine's 2004 report clearly dispelled any link between MMR and autism.

Perhaps the most compelling argument that the MMR vaccine does NOT cause autism is Japan—in 1993, that country stopped using the combination MMR vaccine. Instead, Japanese children were given three separate shots for these diseases. Despite this change, autism rates in Japan continue to rise.[17]

The hysteria surrounding the MMR vaccine and the false 1998 report did have one serious consequence in England: a sharp rise in measles, mumps, and rubella after parents stopped giving their kids the vaccine. In 2004, only 80% of children in the U.K. were vaccinated against MMR. And look at the rise in cases of mumps: 1995: 1936 cases; 2003: 4265 cases; 2004: 15,503 cases.

And remember, autism rates are rising in the U.K. as well. So, now they've got both autism AND vaccine-preventable diseases. It's a lose-lose battle—and the casualties are kids.

Here's the bottom line: as a doctor who sees a large volume of kids, I have never seen a perfectly normally developing kid walk into my office, get his MMR vaccine . . . and come back next week with autism. doesn't happen.

Are we giving too many vaccines today, too soon?

More vaccines are actually a GOOD thing! Every new vaccine protects more kids from getting sick . . . expensive hospital stays . . . and perhaps death or permanent injury. More kids are prevented from getting devastating diseases than ever before, thanks to vaccines. What about getting several shots at once? Is that dangerous? Could you overload a child's immune system with these vaccine germs?

Look at it this way: your child is exposed to thousands of germs on a daily basis (even if he is not in daycare). Exposing your child to five or eight different germs in the form of vaccines is a spit in the bucket. And young kids have a better immune response to vaccines than older children and adults.

Before a vaccine is approved for use by the government, its safety is extensively studied. These studies look at how kids respond to the vaccine. And so-called "combo" vaccines that incorporate several shots at once also consider the combined effect. Even if your child got 11 shots at the same time, he would need to use only about 0.1% of his immune system to respond to the vaccines.

The goal is to protect your child as quickly as possible from diseases that are very dangerous to young children.

And even though the number of shots has gone up, the actual load on the immune system has gone down. That's because today's vaccines are "smarter" and better engineered than the shots from a few decades ago.

Case in point: whooping cough. Before 1991, the whooping cough vaccine had 3000 different germ particles (antigens). Today's whooping ugh shot has just three to five particles—just as effective, but much better designed to be easy on your immune system.

Before 1996, the polio vaccine was "live"—this carried a small risk of actually getting polio. Today's polio vaccine is dead (inactivated) . . . and carries NO chance of transmitting the disease.

So, here's the irony: YOUR parents took much greater risk when getting vaccinated back in the 50's, 60's, and 70's. Today, even though we have many more vaccines, the risk is much lower.

Our children are really getting smarter, safer vaccines today and better protection than we ever got as kids.

BOTTOM LINE: Vaccines do not weaken the immune system, they boost it.

Are there other toxins in vaccines that could cause autism?

Are there additives in the vaccines? Yes. And you should know about them.

Vaccines contain the active ingredients that provide immunity. However, there are inactive ingredients that improve potency and prevent contamination. Here is a list of additives and why they are there.

1. **Preservatives**—prevent vaccine contamination with germs (bacteria, fungus): 2-phen-oxyethanol, phenol.
2. **Adjuvants**—improve potency/immune response: aluminum salts.
3. **Additives**—prevent vaccine deterioration and sticking to the side of the vial: gelatin, albumin, sucrose, lactose, MSG, glycine.
4. **Residuals**—remains of vaccine production process: formaldehyde, antibiotics (neomycin), egg protein, yeast protein.

Now, after reading the above list, you might be freaking out—aluminum salts? MSG? Formaldehyde? We should point out that only TRACE amounts of most of these additives are in vaccines. None have been proven harmful in animals or humans in these amounts.[18]

Reality Check: Should vaccines be "greener"?

If vaccines contain ingredients like aluminum or formaldehyde, wouldn't it be better if vaccine makers got rid of these additives?

We agree that this sounds reasonable—but it doesn't mean that current vaccines are UNSAFE.

Here's the key point: additives like aluminum in vaccines are in EXTREMELY SMALL amounts (often, just a trace). We are all exposed to *significantly higher* levels of environmental toxins in our everyday activities.

Let's look at aluminum. Babies ingest 50 micrograms of aluminum per liter of breast milk . . . and 500 micrograms of aluminum per liter of formula. By contrast, the amount of aluminum in a vaccine is much smaller.

Do you wear antiperspirant? That's got aluminum in it too. And aluminum is found in most food, soil, and water. So, to avoid aluminum exposure, you'd have to stop wearing antiperspirant—and basically leave the planet.

And aluminum poisoning does not cause symptoms of autism, either.[19] Trace amounts (far less than what your baby eats everyday) of aluminum improve the body's immune response to some vaccines. That's why it is in there.

Why is formaldehyde in vaccines? Well, small amounts sterilize the vaccine fluid so your child doesn't get something like the flesh-eating Strep bacteria when he gets his shots.

If you use paper towels or mascara, or have carpeting in your home, you've been exposed to formaldehyde. Obviously, exposure to large amounts of formaldehyde is not a good thing for anyone's health. But, again the amount in vaccines is extremely small.[20]

BOTTOM LINE: Vaccine additives are there for a reason—to make them safer and more effective.

There's so much anti-vaccine stuff online—it's hard to know whom to believe. Can doctors be trusted on this issue?

Most pediatricians are ALSO parents—and docs dedicate their life to protecting kids. If I ever thought vaccines were harming kids, I'd change what I do. I vaccinated my own kids and would do it again in a heartbeat. If you have any doubt about vaccinations, just ask your pediatrician if she vaccinated her kids.

How do you explain the parents who claim their child was perfectly normal and then "something happened"?

It seems like just about everyone's heard one of these heart-wrenching stories—whether it be a child with autism that you know personally, or a celebrity's kid you hear about on TV. The parent reports that the child was developing just fine, until one day the lights just went out. Often, that phrase is accompanied by "after he got his shots."

And understandably, it's enough to make any other parent freak out and think twice when it's time to vaccinate his or her own child.

About 50% of parents with a child affected with autism spectrum disorder believe it was triggered by vaccination. However, the other 50% do not think vaccines had anything to do with it.

Here is what I think, based on what I see in my own practice. Autistic kids were never "typical" to begin with. Not one patient of mine who has ASD was perfectly normal, got a vaccination, and returned the next week with autism. In fact, all the parents in my practice whose children have ASD tell me that they either a) did not recognize the early differences in their child's development or that b) they always knew something was different about their child. The signs just became more apparent over time, the milestones stagnated, or the child seemed to lose skills. About one in five parents will report a loss of milestones. That's what brings it to the parent's attention.

An important fact: above, we noted that one in five parents report a loss in milestones. That means that a vast majority (80%) of kids diagnosed with autism spectrum disorder have no loss of milestones. They start out on a different developmental path and the symptoms become more apparent over time.

One of my ASD patient's moms, who is a medical professional, told me that she realized how clearly different her son's early development was after she watched her second child, without ASD, breeze through her developmental milestones. She had no frame of reference with her first child. And since just about every parent has a camcorder these days, the developmental differences early in a child's life are easily chronicled on videotape for developmental specialists to review. They say the same thing I do. The child was never perfectly normal and these, sometimes, subtle differences are seen before a year of age.

Heck, even the most vocal autism mom of all, Jenny McCarthy, who claimed on Oprah that her son was normal until receiving his combination measles-mumps-rubella vaccine, admits in her book that she missed the early signs of her child's ASD. Specifically, she said that it took her child until he was five months old to smile at her, when her friend's babies all smiled by two months.

One of the leading autism experts in the country has told me that there are, indeed, an extremely small number of ASD children who have completely normal milestones and then regress, which is known as "late onset autism." This type of autism likely represents a subset of children who have a distinct genetic abnormality that turns off spontaneously without any trigger at all. And this distinct group deserves genetic testing and more research.

I know, I know, who are you going to believe? Don't I trust parents and their instincts? Absolutely—you know your kids better than anyone else. But having a child diagnosed with autism is a highly emotion experience. And the diagnosis is usually made around the same time a child is going through his vaccination series. It's true . . . but unrelated. It's true that vaccinations are happening, and it's true that developmental differences become apparent. That doesn't mean they are related. Toddlers are also wearing diapers, drinking whole milk, and hanging out with parents who use cell phones. Do diapers cause autism? How about cell phones or milk? Obviously, no.

And let me be clear, parents aren't the only ones who miss the early signs of autism. Pediatricians do, too. Full developmental assessments are often three to four hours in a specialty referral center. We rely heavily on parents to point out their concerns. Parents and doctors can both miss early signs of autism spectrum disorders in the first year of life. This is one of the key reasons why the American Academy of Pediatrics created an Autism Toolkit in 2007 for its doctors to learn the signs, screen specifically for autism at every well child visit, and provide resources and educational materials for affected children.

BOTTOM LINE: Stoking parents fears about vaccines with false rumors about safety is irresponsible and creates a lose-lose situation for society—and the casualties are children.

Vaccines work. And they are safe. Rather than demonize vaccines, we (doctors, parents, researchers, the government) should put our time, effort, and money into researching the CAUSES of autism and the best possible treatments.

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Vermont Recommended Child & Teen Vaccination Schedule 2011

	Vaccine	Birth	2 Months	4 Months	6 Months	12–15 Months	15–18 Months	Assure your child is up to date by age 2	Prior to Kindergarten: 4–6 Years	Prior to 7th Grade: 11–12 Years	13–18 Years
Required for child care	*Haemophilus influenzae* type b (Hib)		Hib	Hib	Hib	Hib					
Required for child care	Pneumococcal (PCV)		PCV	PCV	PCV	PCV					
Required for school	Hepatitis B (HepB)	HepB	HepB		HepB						
Required for school	Diphtheria, Tetanus, Pertussis (DTaP)		DTaP	DTaP	DTaP		DTaP		DTaP		
Required for school	Poliovirus (Polio) (IPV)		IPV	IPV	IPV				IPV		
Required for school	Measles, Mumps, Rubella (MMR)					MMR			MMR		
Required for school	Varicella (Chicken pox)*					Varicella			Varicella		
Required for school	Tetanus, Diphtheria, Pertussis (Tdap)									Tdap	
Required for school	Meningococcal (MCV4)**									MCV4	MCV4 second dose, after age 16
Recommended	Hepatitis A (HepA)					HepA	HepA				
Recommended	Rotavirus (RV)		RV	RV							
Recommended	Human Papillomavirus (HPV)									HPV 3 doses over 6 months	
Recommended	Influenza				Influenza	Every flu season					

6.2011

* Vaccine or documentation of history of disease.

** Recommended for all. Required only for residential students entering 7th grade and newly enrolled in 8-12.

Vermont's immunization schedule is compatible with the current recommendations of the Advisory Committee on Immunization Practice (ACIP) of the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

For more information, contact the Vermont Department of Health Immunzation Program:

Phone: 802-863-7638 toll free (in VT): 800-640-4374 website: HealthVermont.gov

VERMONT
DEPARTMENT OF HEALTH

Agathe -

Can you give these folders to the Committee Please.

This copy is for you.

Thank you.

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February 23, 2012

Vermont Chiropractic Association Position Paper
On S.199 and H527

S.199 and H.527 seek to remove the philosophical exemption from the current statute in an attempt to improve Vermont's vaccination rate. The Vermont Chiropractic Association opposes removal of the philosophical exemption as a means to achieve this goal. The data from the State suggest that greater focus on completion of vaccination schedules for those who have started them would yield the desired increase in vaccination uptake without stripping individuals and parents of their rights to informed consent.

It has been reported that roughly 40 percent of all children under the age of 3 in Vermont haven't received their mandatory vaccinations and about 20 percent of children entering kindergarten fall into this category. According to a map of non-medical vaccination exemptions on the website of the Vermont Department of Health, Vermont has 4.1%-5.7% non-medical vaccination exemptions for children entering Kindergarten 2009-2010.[1] This data suggests that the reported low rate of vaccinations has much more to do with the non-compliance with the vaccination schedule for preschoolers and much less to do with those who have a philosophical objection to some or all vaccinations.

At what point do the individual's rights succumb to the benefit of society as a whole? Jacobson v. Massachusetts[2] has been quoted and referenced frequently to support compulsory vaccination practices. Jacobson upheld the right of the State over the individual's rights in times of imminent danger and it was argued for only one vaccine for the entire population – not just one segment of the population. Currently, the ACIP (Advisory Committee on Immunization Practices) recommends 16 vaccines totaling 70 doses for children. It is important to note that while these vaccines have been studied individually, they have not been studied for safety of simultaneous administration. Several of the ACIP-recommended vaccines are not for life-threatening diseases (chicken pox) or for diseases contracted during normal social interactions (hepatitis B), yet these vaccines carry risks associated with their administration. The 1986 National Childhood Vaccine Injury Act was enacted to create an infrastructure for a national vaccine program, to insulate manufacturers and the medical profession from liability, to ensure access to affordable vaccines, to establish a program to compensate the injured fairly and generously, and to promote safer vaccines.

In 1988 the National Vaccine Injury Compensation Program (VICP) was created. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. The Vaccine Injury Compensation Trust Fund provides compensation to those

found to be injured by certain vaccines administered on or after October 1, 1988. Since the first Vaccine Injury Compensation claims were made in 1989, 2,853 compensation payments have been made resulting in over 2 billion dollars disbursed to petitioners.[3] The absence of ordinary tort law protection, namely the right to informed consent and the right to sue manufacturers, is riddled with troubling issues.

Before the State removes the rights of an individual for the stated protection of society, it is imperative to consider the context of Jacobson. In all non-emergency situations, parents should retain the right to informed consent. Where the current legal system does not allow for recourse against the manufacturers and risks are undisputed, is it really in the best interest of the both the individual and society to remove the individual's right to informed consent? Removal of the philosophical exemption option for vaccinations would erode prior, free, and informed consent for a medical procedure that inarguably has associated risks. Embedded in and fundamental to informed consent is the option to refuse a treatment or procedure. We strongly support the right to refuse any or all treatments, even if such a refusal is generally viewed as an unwise choice.

We suggest that the State focus its efforts to improve education and compliance with immunization schedules for all preschoolers instead of denying the rights of Vermonters to exercise true informed consent by removing the philosophical exemption.

1. http://www.healthvermont.gov/hc/imm/documents/CDC_National_IZ_NonMedExemptions_K_2009_2010_Final.pdf
2. Jacobson v. Massachusetts, 197 U.S. 11 (1905).
3. http://www.hrsa.gov/vaccinecompensation/index.html

Encl: "Reconsidering Compulsory Childhood Vaccination" – Mary Holland, NYU School of Law, *Hollandm@exchange.law.nyu.edu*

Sincerely,

James R. McDaniel, DC
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9-1-2010

Reconsidering Compulsory Childhood Vaccination

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Reconsidering Compulsory Childhood Vaccination

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ABSTRACT

The laws that govern childhood compulsory vaccination deprive parents and children of three ordinary tort law protections: free and informed consent to an invasive medical procedure; accurate and complete information about vaccine ingredients and possible side effects; and the right to sue manufacturers and medical practitioners directly in the event of injury. While these atypical tort law standards have been adopted and upheld for the public good, this article argues that they have caused unintended and undesirable consequences. These effects include unnecessary compulsory childhood vaccinations; conflicts of interest in national vaccine policy; inadequate vaccine safety; inadequate warnings about vaccine risks; insufficient compensation for vaccine-induced injury; and other undesirable outcomes. The article offers a new interpretation of the landmark Supreme Court case, Jacobson v. Massachusetts, that recognizes constitutional limitations on compulsory vaccination, and sheds light on the key federal statute, the National Childhood Vaccine Injury Compensation Act.

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[1] Director, Graduate Legal Skills Program. I am grateful to the NYU Lawyering Program Colloquium and the Center for Personal Rights Colloquium for opportunities to discuss this article. Special thanks to Kevin Barry, Joy Radice, Kim Mack Rosenberg, Jenny Roberts and Juliet Stumpf for critique. I am grateful to Heather Groves for invaluable research assistance.

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In 1995, within hours of receiving a diphtheria, tetanus and pertussis vaccine, infant Hannah Bruesewitz had life-threatening seizures. She continues to suffer severe seizures and multiple impairments. Her parents timely filed a claim in the Vaccine Injury Compensation Program (VICP) but they were denied compensation for failure to prove causation. The family then sued in civil court on a vaccine design defect theory. The district court dismissed the claim and the Third Circuit Court of Appeals affirmed. The U.S. Supreme Court will hear her appeal on October 12, 2010. It will decide whether the Bruesewitzes have the right to sue the vaccine manufacturer in civil court under the 1986 National Childhood Vaccine Injury Compensation Act.[2]

INTRODUCTION

"Vaccines save lives" is what American government, medicine and culture teach us. While true for the majority, it is also true that vaccines may injure, disable and cause death to some. Compulsory vaccination of children spotlights the moral and legal limits on state coercion of individuals. How far can the government go to compel vaccination? Whom may it compel? And on what grounds? And when vaccines do cause permanent damage, who bears the financial cost? And if vaccines are defective, what then? These questions potentially affect millions of Americans as almost all children receive 30-45 compulsory vaccines to attend school.[3] More than ten thousand people have sought compensation for vaccine injury to date.[4] The U.S. Supreme Court will hear issues bearing on vaccine injury in October, 2010 in *Bruesewitz v. Wyeth*, the case briefly outlined above.

The purpose of compulsory vaccination is to protect children and the public from infectious disease. Indeed, vaccines are widely credited as one of the most important contributions of modern medicine.[5] The role of vaccines in protecting children and the public may be overstated, however, in that the mortality rates from infectious disease dropped precipitously in the twentieth century before almost any vaccines were in widespread use in the

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[2] Bruesewitz v. Wyeth Inc., 561 F.3d 233 (3rd Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

[3] *See* National Network for Immunization, State Requirements, http://www.immunizationinfo.org/vaccines/state-requirements.

[4] National Vaccine Injury Compensation Program, Statistics Report, Health Resources and Services Administration (July 14, 2010), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (reporting that 13,479 petitions were filed between fiscal years 1988 and 2010, 7,409 petitions have been dismissed and 2,472 have been compensated as of July 14, 2010).

[5] *Ten Great Public Health Achievements – United States, 1900-1999*, MORBIDITY & MORTALITY WKLY R. (1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm (listing vaccination first).

United States.[6] These dramatic declines were likely due to better sanitation, cleaner water, better overall nutrition and the availability of antibiotic and antiviral medicines.[7]

Compulsory vaccination laws have been a central pillar of government policy because the government attributes near eradication of childhood infection diseases primarily to universal vaccination. But while compulsory vaccination may serve the greater good, state and federal laws deprive American school children and their parents of three ordinary tort law protections: free and informed consent to an invasive medical procedure; accurate and complete information about vaccine ingredients and possible side effects; and the right to sue manufacturers and medical practitioners directly in the event of injury.[8] The absence of these legal protections is striking compared to almost all other medical interventions. Because of the perceived overwhelming benefit from vaccines, U.S. federal and state law treat compulsory vaccination of children in a radically different way. Compulsory childhood vaccination is the most salient deviation from the ethical and professional standard of informed consent in civilian medicine.

Three laws are at the core of the national childhood vaccine program: *Jacobson v. Massachusetts*, a landmark 1905 Supreme Court decision; *Zucht v. King*, a 1922 Supreme Court case; and the 1986 National Childhood Vaccine Injury Compensation Act (the 1986 Law or Law). *Jacobson* established a state's police power to compel vaccination.[9] *Zucht* upheld vaccination mandates as a condition for school attendance.[10] And the 1986 Law created the modern national vaccine program: the infrastructure for mass childhood vaccination;[11] insulation of vaccine manufacturers and medical practitioners from ordinary tort liability;[12] removal of the right to accurate and complete information;[13] establishment of a program to compensate vaccine-injured victims;[14] and the obligation to make safer vaccines.[15]

The legal framework for compulsory childhood vaccination is similar in some ways to the legal regimes for housing finance, banking and oil drilling which have recently experienced severe crises.[16] Like those sectors, the vaccine industry has largely 'captured' its regulators; the

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[6] *See, e.g.*, Gregory L. Armstrong et al., *Trends in Infectious Disease Mortality in the United States During the 20th Century*, 281 J. AM. MED. ASS'N (Jan. 6, 1999), http://jama.ama-assn.org/cgi/ content/full/281/1/61 (including graphs showing steep declines in infectious disease in the twentieth century).

[7] *Id.* at *Comment* section ("During the first 8 decades of the 20th century, the infectious disease mortality rate in the United States declined substantially....Improvements in living conditions, sanitation, and medical care probably accounted for this trend.")

[8] 42 U.S.C. § 300aa-1 *et seq.* (2010)

[9] Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[10] Zucht v. King, 260 U.S. 174 (1922).

[11] National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-2 (1986 Law).

[12] *Id.* § 300aa-11.

[13] *Id.* § 300aa-22(c) (removing manufacturer liability for failure to directly warn injured parties of dangers that may result from administration of vaccines); Id. § 300aa-26 (requiring Secretary to disseminate information).

[14] *Id.* § 300aa-10.

[15] *Id.* § 300aa-27.

[16] *See, e.g., Credit Crisis – The Essentials*, N.Y. TIMES, July 12, 2010, at http://topics.nytimes.com/top/ reference/timestopics/subjects/c/credit_crisis/index.html (noting that President Obama, during his campaign, blamed

sector is deemed 'too important to fail;' credible experts recognize serious safety concerns; and designated corporate and governmental funds are almost certain to be insufficient if vaccines are definitively linked to disorders with which they have been associated, including developmental disabilities and asthma.[17] Without change, the national vaccine program could confront similar legal challenges to those that now face the housing, banking and oil drilling sectors. If such crises occur, the public will ask how such grave unintended consequences could have been happened.

This article argues that the absence of ordinary tort law protection in the national childhood vaccine program, namely, the rights to informed consent and to sue manufacturers and doctors directly, is associated with troubling facts. These facts include conflicts of interest; inadequate safety; inadequate compensation to vaccine-injured children; inadequate vaccine warnings; and problems in children's health. The article argues that current vaccination mandates abuse state police powers and violate *Jacobson* because they fail to require public health necessity. It suggests that childhood vaccine mandates today are so radically different than what *Jacobson* upheld that courts may be required to step in. No articles to date have made similar claims.

Part I looks at Supreme Court decisions which authorize state compulsion of school vaccination mandates and the legal developments before the enactment of the 1986 Law. Part II looks at the 1986 Law and its liability and information protections for industry and medical practitioners. Part III examines the unintended consequences of these laws. Part IV briefly addresses ways to challenge *Jacobson* and amend the 1986 Law to better safeguard children.

I. State Police Power to Compel Childhood Vaccination

A. Judicial Decisions before *Jacobson v. Massachusetts*

Infectious disease was a leading cause of death in the United States until the 20th century. During the 19th century, movement from the countryside to cities, with poor housing and inadequate sanitation and drinking water, spurred outbreaks of infectious disease.[18] These conditions resulted in repeated outbreaks of infectious disease, such as cholera, typhoid,

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the credit crisis on government deregulation, explaining the relationship between the housing and mortgage crisis and the meltdown of various financial institutions, and describing the multi-billion dollar government bailout programs designed to keep banks from failing); *See also* David Barstow et al., *Regulators Failed to Address Risks in Oil Rig Fail-Safe Device*, N.Y. TIMES, June 20, 2010, at http://www.nytimes.com/2010/06/21/us/21blowout.html (describing how the Gulf oil spill could have possibly been prevented had more stringent regulations been in place and enforced).

[17] *See, e.g.*, Carolyn Gallagher & Melody Goodman, *Hepatitis B Triple Series Vaccine and Developmental Disability in US Children Aged 1-9 Years*, 90 TOXICOLOGICAL & ENVTL. CHEMISTRY 997 (2008); Kara L. McDonald et al., *Delay in Diphtheria, Pertussis, Tetanus Vaccination Is Associated With a Reduced Risk of Childhood Asthma*, 121 J. ALLERGY & CLINICAL IMMUNOLOGY 626 (2008).

[18] *Achievements in Public Health, 1900-1999: Control of Infectious Diseases*, 48 MORBIDITY & MORTALITY WKLY. REP. 621, 621 (1999).

influenza and malaria. In 1900, more than 30% of all deaths occurred among children under five years old.[19] Although vaccination carried risks, the practice became widespread in Europe and the United States in the 1800s as a preventive health measure against smallpox, a deadly, contagious, airborne disease.[20] In the nineteenth century, vaccination against smallpox meant introducing a milder form of the disease, cowpox, into individuals and inducing an immune response intended to prevent the recipient from getting smallpox. If a vaccination subject received a sufficiently strong immune response, he would not contract smallpox over several years, even if repeatedly exposed to it.[21] Compulsory smallpox vaccination was introduced in some jurisdictions in the 1800's to ensure 85-95% rates of vaccination in the population in order to achieve "herd immunity," intended to deter or prevent the spread of disease throughout the population.[22]

Vaccination mandates are laws requiring individuals to be vaccinated or face penalties, such as a fine or the loss of the right to attend public school. Before *Jacobson*, state statutes on vaccination varied. In 1905, eleven states had compulsory vaccination mandates for smallpox but the majority, thirty-four states, did not. No states had laws that forced vaccination on unwilling subjects. In other words, no states had laws to forcibly vaccinate individuals, although this practice reportedly did occur.[23]

Judicial decisions interpreting state laws on vaccination before *Jacobson* were similarly diverse. In 1894, the Pennsylvania Supreme Court upheld the right of the state to exclude unvaccinated children from school during a smallpox epidemic but took pains to point out that the state could not physically force vaccination. It simply upheld the regulation to exclude unvaccinated children during an epidemic for the public health.[24] In 1900, the Utah Supreme Court similarly upheld an exclusion order for an unvaccinated child, but this majority opinion prompted a strong dissent, noting that the exclusion rule was "an attempt, indirectly, to make vaccination compulsory" and that the medical board had no such authority.[25] In 1902, the Minnesota Supreme Court upheld a school exclusion rule for an unvaccinated child, but made clear that its ruling was narrow and permissible "in cases of emergency only."[26] In 1900, a California court established that no vaccination mandate could be applied in a racially

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[19] *Id.* at 621.

[20] *Jacobson*, 197 U.S. at 34 ("'Smallpox is known of all to be a dangerous and contagious disease.'" (quoting Viemeister v. White, 84 N.Y.S. 712 (N.Y. App. Div. 1903))).

[21] *Id.*

[22] Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37:2 U. MICH. J.L. REFORM 353, 419-421 (2004) (describing herd immunity).

[23] *See e.g.*, Michael Willrich, *"The Least Vaccinated of Any Civilized Country": Personal Liberty and Public Health in the Progressive Era*, 20 J. POL'Y HIST. 76, 85-86 (2008) ("The local health authorities carried out the orders during a public health emergency, and their impatience with resistance led easily to violence, including many documented cases of physical-force vaccination.").

[24] Duffield v. Williamsport Sch. Dist., 29 A. 742 (Pa. 1894).

[25] Cox v. Bd. of Educ., 60 P. 1013, 1020 (Utah 1900).

[26] Freeman v. Zimmerman, 90 N.W. 783, 784 (Minn. 1902).

discriminatory manner because it would violate the equal protection clause of the 14th Amendment to the Constitution.[27]

In 1903, New York's highest court opined that the state's mandate for school vaccination and its state constitutional right to a public education were compatible provisions. It construed the state constitution's language "[t]he Legislature shall provide for the maintenance and support of a system of free common schools, wherein all the children of this State may be educated" as a privilege, not a right. It reasoned that because all pupils were subject to the same vaccination obligation, the state met constitutional due process and equal protection guarantees. It further suggested that courts owe great deference to legislatures on such questions. It relied on decisions of several other courts that found that state constitutional guarantees of education did not contradict vaccination mandates, even when there was no imminent threat of disease.[28]

While judicial decisions before *Jacobson* never forced vaccination, they often justified existing mandates, whether for adults or children, and upheld exclusion of unvaccinated children from public school during epidemics. Some courts spoke explicitly of the need to show necessity and emergency; others took a more expansive view, leaving broad discretion to the legislatures on matters of public health. In short, there was an emerging judicial consensus to uphold vaccination mandates, but the overwhelming majority of states did not impose them. And in any event, at issue was always just one vaccine against smallpox.

B. *Jacobson v. Massachusetts*

Unlike in 1905, today there are vaccination mandates for school admission in 50 states,[29] mandates for certain categories of adults, such as healthcare workers;[30] and public health emergency acts with vaccination provisions in many states.[31] Decided by the Supreme Court in

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[27] Wong Wai v. Williamson, 103 F. 1 (N.D. Cal. 1900).

[28] Viemeister v. White, 84 N.Y.S. 712, 712 (N.Y. App. Div. 1903) (citing Abeel v. Clark, 24 P. 383 (Cal. 1890); Duffield v. Williamsport Sch. Dist., 29 A. 742 (Pa. 1894); Field v. Robinson, 48 A. 873 (Pa. 1901); Bissell v. Davison, 32 A. 348 (Conn. 1894); Blue v. Beach, 56 N.E. 89 (Ind. 1900); *In re* Rebenack, 62 Mo. App. 8 (Mo. Ct. App. 1895).

[29] James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 833 (2001-02) ("Each state has school vaccination laws which require children of appropriate age to be vaccinated for several communicable diseases.").

[30] The CDC provides information on states' requirements for healthcare workers and patients. Vaccines & Immunizations: State Immunization Laws for Healthcare Workers and Patients, Centers for Disease Control and Prevention (Apr. 2010), http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/default.asp. For instance, in New York, hospital employees must be offered Hepatitis B vaccine, and are required to be vaccinated against measles, mumps, rubella, and influenza. Vaccines & Immunizations, Immunization Administration Requirements For State: NY, Centers for Disease Control and Prevention (May 3, 2010), http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/Administration.asp?statetmp=NY.

[31] *See* James G. Hodge, Jr., and Lawrence O. Gostin, *The Model State Emergency Health Powers Act - A Brief Commentary* (January 2002) , http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf (last visited Sept. 6, 2010).

1905, *Jacobson* has been interpreted to mean that states may impose reasonable regulations to ensure the public health and safety, even if such regulations infringe individuals' personal liberty. Because of the fundamental character of this decision justifying vaccination public health measures today, the article examines the decision in detail.

Jacobson came to the Supreme Court from the Massachusetts Supreme Court, which upheld the validity of a Cambridge, Massachusetts mandate to compel smallpox vaccination for all adults on penalty of a $5 fine (the equivalent of about $110 today).[32] Mr. Jacobson refused to comply with the regulation and would neither agree to be vaccinated nor pay the $5 fine. Mr. Jacobson argued that the regulation violated his rights under the 5th and 14th Amendments.[33] He argued that the state mandate threatened his life, liberty and property and deprived him of the due process and equal protection of the law. In essence, he argued that his right to bodily integrity and personal liberty trumped the state's right to impose a vaccination in the name of public health.

In upholding the Cambridge regulation, the Supreme Court reasoned that constitutional protection of individuals is not unlimited and that states retain police powers to ensure public health and safety. The Court argued that states retain the right to issue reasonable regulations and that in the context of a smallpox epidemic, Cambridge's ordinance was not "unreasonable, arbitrary or oppressive."[34] The Court argued that it was the legitimate province of the legislature to decide what measures would be best, and that the legislature was unquestionably aware of opposing views about vaccination among the medical profession and the electorate. The Court pointed out that the regulation required the inhabitants to be vaccinated only when "that was necessary for the public health or the public safety."[35] The Court found that the regulation did not violate the 14th Amendment because it was "applicable equally to all in like condition."[36] The Court analogized the state's police power to impose a vaccination mandate to its power to enforce quarantines and to the federal government's right to impose a military draft.[37]

Contemporary public health discourse commemorates the first part of the decision but often fails to note the second. The second half describes what would constitute potential abuse of the police power. The Court did not give states blind deference. The Court justified the Cambridge regulation as reasonable, imposing one vaccine, on an emergency basis, on the entire adult population, in the context of a contagious, deadly epidemic, with a relatively small fine for

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[32] The Consumer Price Index was started in 1913 to track changes in prices of consumer goods. A government inflation calculator indicates that $5 in 1913 would be the same as about $110.11 in 2010. Bureau of Labor Statistics: CPI Inflation Calculator, http://www.bls.gov/data/inflation_calculator.htm.

[33] "No state shall make nor enforce any law abridging the privileges or immunities of citizens of the United States nor deprive any person of life, liberty or property without due process of law, nor deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. amend. XIV, § 1.

[34] *Jacobson*, 197 U.S. at 27.

[35] *Id.*

[36] *Id.*

[37] *Id.* at 29-30.

non-compliance. The Court's paradigm was clear: a mandate in "an emergency;"[38] when there was "imminent danger;"[39] when "an epidemic of disease...threatens the safety of [society's] members;"[40] when there was "the pressure of great dangers"[41] and an "epidemic that imperiled an entire population."[42]

Describing potential abuse of police power, the Court opined:

> [a regulation] might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.[43]

The Court noted cases when state laws "went beyond the necessity of the case, and, under the guise of exerting a police power...violated rights secured by the Constitution."[44] The Court noted:

> there is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will.[45]

The Court cautioned that if a state statute purported to have been enacted for the public health, but "has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the court to so adjudge."[46] The Court anticipated the possibility that the police power to vaccinate might be exerted in circumstances when regulations could be "so arbitrary and oppressive...as to justify the interference of the courts to prevent wrong and oppression."[47]

The Court expressly created a medical exemption from vaccination, when a person was not a fit subject for vaccination and it "would be cruel and inhuman in the last degree" to vaccinate him.[48] Because of *Jacobson*, medical exemptions exist in all 50 states.[49] The Court

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[38] *Id.*
[39] *Id* at 29.
[40] *Id.* at 27.
[41] *Id.* at 28.
[42] *Id.* at 31.
[43] *Id.* at 28 (*citing* Wis., Minn., & Pac. R.R. v. Jacobson, 179 U.S. 287 (1900)).
[44] *Id.*
[45] *Id* at 29.
[46] *Id.* at 31.
[47] *Id.* at 38.
[48] *Id* at 39.
[49] Hodge & Gostin, *supra note* 29 at 874 ("While the statutory provisions vary from state to state, all school immunization laws grant exemptions to children with medical contra-indications to immunization, consistent with

also specifically approved that the statute granted special medical exemption to children. It wrote that "there are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years."[50] In other words, it approved the Massachusetts regulation which granted infants and children greater protection from compulsion than adults.

Although the Court was clearly wary of treading in areas of legislative competence, it proclaimed the right, indeed the responsibility, to give sensible construction to any regulation so that it would not lead to "injustice, oppression, or an absurd consequence."[51] It made clear that no law should be interpreted in practice to be "cruel and inhuman in the last degree."[52]

While subsequent courts have interpreted *Jacobson* to justify regulations beyond necessity to prevent potential disease, *Jacobson* itself sounded the alarm that courts should be vigilant to examine and thwart unreasonable assertions of state power.

C. *Jacobson*'s Application

Initial application of *Jacobson* was circumspect. From 1907 to 1914, state appellate and supreme courts construed *Jacobson* as permitting single vaccination mandates during smallpox outbreaks.[53] The courts upheld mandates and exclusion of unvaccinated school children during emergencies. These decisions applied the "arbitrary, unreasonable and oppressive" standard and looked for evidence of public necessity, and particularly the threat of epidemic.[54] These decisions found that statutes that did not include medical exemptions had to be read to contain them.[55] The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.[56]

Beginning in 1916, however, judicial interpretations of *Jacobson* started to broaden. The Alabama Supreme Court read into *Jacobson* the implied power to prevent epidemics, not simply to respond to existing ones. A father sued the school board for excluding his unvaccinated daughter from school when there was no smallpox epidemic.[57] The court upheld the state's delegation of authority to the school board and the state's right to prevent disease. The decision also argued that mandates of children and not adults – the opposite of the mandate in question in

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the judicial and ethical principles of harm avoidance asserted by the Supreme Court in *Jacobson v. Massachusetts*.").

[50] *Jacobson*, 197 U.S. at 30.

[51] *Id.* at 39.

[52] *Id.*

[53] Hammond v. Inhabitants of Hyde Park, 80 N.E. 650 (Mass. 1907); O'Bannon v. Cole, 119 S.W. 424 (Mo. 1909); McFadden v. Shorrock, 104 P. 214 (Wash. 1909); McSween v. Bd. of Sch. Trs., 129 S.W. 206 (Tex. 1910); People v. Ekerold, 105 N.E. 670 (N.Y. 1914).

[54] *O'Bannon*, 119 S.W. at 427.

[55] *McFadden*, 104 P. at 216.

[56] *Hammond*, 80 N.E. at 651.

[57] Herbert v. Bd. of Educ., 73 So. 321 (Ala. 1916).

Jacobson – were valid because groups of children "constitute[e] a condition different, with respect to hygienic circumstances, effects, and results, from that to be found in any other character of assemblage in a municipality."[58] The court deferred to municipal authorities on public health.[59]

The Kentucky Supreme Court reached a similar conclusion, finding that boards "are not required to wait until an epidemic actually exists before taking action. Indeed, one of the chief purposes of their existence is to adopt and enforce such timely measures as will prevent epidemics."[60] These decisions interpreted *Jacobson* broadly; in neither situation was there an imminent danger or necessity for the state to act in self-defense. While these decisions authorized preventive measures, they did not impose insurmountable burdens: they imposed one vaccine when smallpox was still in circulation.

1. *Zucht v. King*: Applying *Jacobson* to School Mandates

In 1922, the Supreme Court held in *Zucht v. King* that a smallpox vaccination mandate for school admission was a valid exercise of the police power.[61] In a cursory, unanimous decision, the Court cited to *Jacobson* as settling that compulsory vaccination may be a requirement of public school admission.[62] The Court denied the petitioner's claim of infringement of her 5th and 14th Amendment rights based on *Jacobson*.[63] It considered, though, that the law might have been administered in a way that violated her rights.[64] Nonetheless, the Court found that the school vaccination mandate had not conferred arbitrary power but "only that broad discretion required for the protection of the public health."[65] The Court did not inquire into the circumstances of the epidemic and affirmed substantial deference to school boards, with smallpox as the relevant, but unnamed, backdrop.

Zucht did not alter *Jacobson*'s fundamental analysis that necessity is required to justify state police powers – it simply applied this analysis to schools specifically. Whether because the Justices thought that *Jacobson*'s analysis was sufficient, or because smallpox posed an obvious risk, the Supreme Court affirmed the mandate without detailed discussion. Indeed, *Zucht* is a three paragraph decision presumably intended to stop judicial challenges to school smallpox vaccination mandates. But *Zucht* did shift *Jacobson*'s paradigm somewhat, by upholding a mandate exclusively for children and not for the entire population. Still, *Zucht* did not lower *Jacobson*'s threshold of necessity to compel vaccination.

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[58] *Id.* at 323.
[59] *Id.*
[60] Bd. of Trs. v. McMurtry, 184 S.W. 390, 394 (Ky. 1916).
[61] Zucht, 260 U.S. at 176.
[62] *Id.* at 176.
[63] *Id.*
[64] *Id.* at 177.
[65] *Id.*

2. Early Interpretation of *Jacobson*

In the early 1900's, several courts rejected expansive interpretations of *Jacobson.* Courts did not universally approve of legislatures' broad discretion to require vaccination mandates outside of emergencies. In 1919, the Supreme Court of North Dakota struck down a school mandate to exclude unvaccinated children when there was no imminent threat.[66] This court decided that boards of health "cannot promulgate and enforce rules which merely have a tendency [to prevent disease]...but which are not founded upon any existing condition or danger reasonably to be apprehended."[67]

A concurrence in this North Dakota case went farther, arguing that "child vaccination in a state where smallpox does not prevail...has no excuse; it is a barbarism." [68] The concurrence focused on the responsibility of courts to protect civil liberties from abuses of state power and warned against judges "too ready to follow the example of Pontius Pilate – to wash their hands – and to blame a supposed law or a precedent for their unjust decisions."[69] The judge noted the central roles of better sanitation, clean water and nutrition in public health and the self-interest of the medical profession and manufacturers in vaccination mandates. He noted, in 1919, the potential for conflicts of interest:

> Of course a different story [than the story about vaccine risks] is told by the class that reap a golden harvest from vaccination and the diseases caused by it. Yet, because of their self-interest, their doctrine must be received with the greatest care and scrutiny. Every person of common sense and observation must know that it is not the welfare of the children that causes the vaccinators to preach their doctrines and to incur the expense of lobbying for vaccination statutes....And if anyone says to the contrary, he either does not know the facts, or he has no regard for the truth.[70]

But his cautionary view was not the predominant one.

The dominant trend adopted an expansive reading of state police powers for public health. In 1923, in a Texas decision, the court's majority disallowed the medical vaccination certificate of a child who had been immunized using a homeopathic technique. The court cited to *Jacobson* for the proposition that health boards may dictate the method as well as the requirement of vaccination as a legitimate restraint on liberty.[71] This Texas court majority

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[66] Rhea v. Bd. of Educ., 171 N.W. 103 (N.D. 1919).
[67] *Id.* at 106.
[68] *Id.* at 107 (Birdzell, J., concurring).
[69] *Id.* at 108.
[70] *Rhea*, 171 N.W. at 107 (Birdzell, J., concurring).
[71] Abney v. Fox, 250 S.W. 210 (Tex. App. 1923).

decision prompted a strong dissent, arguing that "necessity is the source of the authority to require vaccination, and no such authority exists where it is conceded that no such necessity exists."[72] The dissent cited to *Jacobson*'s cautionary language.

3. Later Interpretation of *Jacobson*

By 1934, courts read *Jacobson* to validate preventive smallpox mandates.[73] The Mississippi Supreme Court granted discretion to public health authorities, stating "the presumption is in favor of the reasonableness and propriety of regulations enacted in pursuance of such grant of power."[74] A 1934 Texas case decided that it could not evaluate whether an emergency existed.[75] Rather, it held "we cannot attempt to measure how pressing a necessity must be in order to allow the board's discretion to be exercised."[76] That court flatly rejected the idea that the court could assess emergency.[77]

Courts increasingly abdicated the role to assess the reasonableness of the state's exercise of police powers. For instance, the New Jersey Supreme Court, in upholding a vaccination mandate, held that "the question of the desirability or efficacy of compulsory vaccination...and whether it is wise or unwise is strictly a legislative and not a judicial question."[78] The Court read *Jacobson* to justify all vaccination mandates, disregarding its language to reject unreasonable, arbitrary or oppressive state actions.[79]

A 1951 Arkansas case, asked to evaluate the validity of a preventive vaccination mandate, decided that it was not the court's place to judge the efficacy or safety of vaccinations.[80] The court even suggested that the plaintiffs lodge objections with the Board of Health rather than the court.[81]

By the mid-1950's, it was arguably a settled interpretation of law that vaccination mandates were presumptively valid, regardless of emergency. *Jacobson*'s robust cautionary language had been all but erased from the precedent's application. In 1964, the Arkansas Supreme Court held that parents had no legal right to refuse vaccination of their children. The court removed children from the father's custody, placed them with a guardian, and ordered them to be forcibly vaccinated.[82] The Arkansas court did not recognize the validity of the children's religious exemptions, and in referring to *Jacobson*, reasoned that "it is within the police power of

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[72] *Id.* at 214 (Key, C.J., dissenting).
[73] Hartman v. May, 151 So. 737 (Miss. 1934).
[74] *Id.* at 739.
[75] Booth v. Bd. of Educ., 70 S.W.2d 350 (Tex. Civ. App. 1934).
[76] *Id.* at 353.
[77] *Id.*
[78] Sadlock v. Bd. of Educ., 58 A.2d 218, 220 (N.J. 1948).
[79] *Id.*
[80] Seubold v. Fort Smith Special Sch. Dist., 237 S.W.2d 884, 887 (Ark. 1951).
[81] *Id.*
[82] Cude v. State, 377 S.W.2d 816 (Ark. 1964).

the State to require that school children be vaccinated against smallpox....In fact, this principle is so firmly settled that no extensive discussion is required."[83] The Arkansas Supreme Court upheld the prosecutor's charge of child neglect against the father who refused to vaccinate his children on religious grounds.

Jacobson does not justify forced vaccination of adults or children. Indeed, by contrast, *Jacobson* upheld the validity of a monetary penalty on an adult for non-compliance. *Jacobson* does not justify a forced medical intervention that could, depending on individual constitution, lead to a result "cruel and inhuman in the last degree."[84] On the contrary, *Jacobson*, by upholding a fine for non-compliance, implied that to force vaccination would be in "a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will."[85]

Potential plaintiffs have elected not to challenge *Jacobson* directly over many decades, perhaps because of overbroad judicial interpretation and extreme deference to states for preventive school vaccination.[86] Given courts' deference to legislatures and agencies, potential plaintiffs opposing vaccination mandates presumably considered direct challenges futile. Instead, since the 1960's when states began to compel children to receive six or more vaccines in multiple doses, litigation has centered on exemptions. Forty-eight of the fifty states provide for religious exemption from vaccination mandates.[87] Cases before courts have considered whether membership in an unrecognized faith justifies religious exemption;[88] whether exclusion of unvaccinated children from school following a measles outbreak is justified;[89] whether a parent's religious objections to vaccination are sincerely held;[90] whether religious exemptions violate the First Amendment establishment clause;[91] and whether state law with no religious exemption violates the First, Fifth and Fourteenth Amendments.[92]

Since the 1960's, states have sometimes punished non-compliant parents harshly. Even when religious exemptions exist, courts have sometimes found parents liable for child neglect

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[83] *Id.* at 819.
[84] Jacobson, *supra* note 9.
[85] Jacobson, *supra* note 9.
[86] *See* ROBERT D. JOHNSTON, THE RADICAL MIDDLE CLASS: POPULIST DEMOCRACY AND THE QUESTION OF CAPITALISM IN PROGRESSIVE ERA PORTLAND, OREGON PAGE (2003); *see also* Willrich, *supra* note 23.
[87] *See, e.g.*, States With Religious and Philosophical Exemptions from School Immunization Requirements, National Conference of State Legislatures (June 2010), http://www.ncsl.org/IssuesResearch/Health/SchoolImmunization ExemptionLaws/tabid/14376/Default.aspx; Hodge & Gostin, *supra* note 29, at 44, n.233.
[88] Brown v. Stone, 378 So.2d 218 (Miss. 1979).
[89] Maricopa County Health Dept. v. Harmon, 750 P.2d 1364 (Az. Ct. App. 1987).
[90] LePage v. State, 18 P.3d 1177 (Wyo. 2001).
[91] McCarthy v. Boozman, 212 F. Supp. 2d 945 (E.D. Ark. 2002); Boone v. Boozman, 217 F. Supp. 2d 938 (E.D. Ark. 2002).
[92] Workman v. Mingo County Schs., 667 F. Supp. 2d 679 (S.D.W.Va. 2009).

when they refuse to vaccinate their children.[93] Courts have mandated child removal and forced vaccination of children in families who have asserted religious objections.[94]

Current interpretations of *Jacobson* justify results *Jacobson* did not: multiple preventive vaccination mandates exclusively for children, in the absence of public health emergencies and extreme penalties for non-compliance. Punishments include loss of education, social isolation, parents' loss of custodial rights, child neglect sanctions against parents, and even forced vaccination. In *Jacobson* and *Zucht*, the Supreme Court upheld mandates with one vaccine during public epidemics. States and courts have moved far from the original *Jacobson* precedent.

D. Scholarly Interpretation of *Jacobson*

The one hundredth anniversary of *Jacobson* in 2005 prompted a retrospective on the decision's continuing impact in the *American Journal of Public Health,* the leading journal for public health.[95] The contributors applauded the decision for providing a set of legal balancing tests for public health decisions. Professor Gostin, a prominent expert on public health and vaccination law asked, "Would *Jacobson* be decided the same way if it were presented to the Court today?" He answered, "indisputably *yes*, even if the style and the reasoning would differ."[96]

Professors Mariner, Annas and Glantz took a different view, arguing that a mandatory vaccination mandate today "to prevent dangerous contagious diseases in the absence of an epidemic" would probably be upheld "as long as (1) the disease still exists in the population where it can spread and cause serious injury to those infected, and (2) a safe and effective vaccine could prevent transmission to others."[97] In their view,

> Public health programs that are based on force are a relic of the 19th century; 21st century public health depends on good science, good communication, and trust in public health officials to tell the truth. In each of these spheres, constitutional rights are the ally rather than the enemy of public health. Preserving the public's health in the 21st century requires preserving respect for personal liberty.[98]

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[93] *In re* Elwell, 284 N.Y.S.2d 924 (N.Y. Fam. Ct. 1967); *In re* Christine M., 595 N.Y.S.2d 606 (N.Y. Fam. Ct. 1992).

[94] *Cude*, 377 S.W.2d at 821.

[95] James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of* Jacobson v. Massachusetts, 95 AM. J. PUB. HEALTH 571 (2005); Lawrence O. Gostin, Jacobson v. Massachusetts *at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576 (2005); Wendy K. Mariner *et al.*, Jacobson v. Massachusetts*: It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581 (2005).

[96] *Id.*, Gostin, at 580.

[97] Mariner *et. al.*, *supra* note 95, at 586.

[98] *Id.* at 588.

While acknowledging the benefits of voluntary compliance and respect for human rights, a third essay argued that *Jacobson* accurately reflected the real trade-offs that may be necessary between individual rights and public health. Professors Colgrove and Bayer suggested that *Jacobson* appropriately confronted the tensions between the state and the individual, and that only through such a confrontation "can a clear understanding about the potential costs of public health policy emerge."[99] These retrospectives contemplated mandates for the whole population, however, and not how *Jacobson* is applied – almost exclusively on children through compulsory vaccination for school.

On the issue of school vaccination mandates, most scholars today praise mandates and attribute to them the near eradication of childhood infectious diseases, without consideration of other factors, such as sanitation, hygiene, nutrition and the availability of other medical interventions, such as antibiotics.[100] They express grave concerns about exemptions from vaccination mandates that might diminish herd immunity. Many argue that there should be no religious exemptions to vaccination mandates[101] and that all non-medical exemptions should be contingent on state discretion.[102] Unlike this author, most commentators do not perceive in today's childhood vaccination program the dangers to which *Jacobson* alluded.

E. Legal Developments Leading to the 1986 Law

Vaccination mandates became legally well-entrenched when there was only one and when smallpox was a life-threatening, contagious disease. By the 1950's, when the polio vaccine became available, health officials opted for persuasion rather than compulsion to achieve compliance. Only a minority of states passed polio mandates. The National Foundation for

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[99] Colgrove & Bayer, *supra* note 95, at 575.

[100] Daniel A. Salmon et. al., *Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future*, 367 LANCET 436 (2006) ("Vaccination is one of the greatest achievements in medicine and public health: wild-type poliovirus will soon be eradicated and each year, about 5 million life-years are saved by control of poliomyelitis, measles, and tetanus."); Hodge & Gostin, *supra* note 29, at 875 ("The incidence of common childhood illnesses (such as measles, pertussis, mumps, rubella, diphtheria, tetanus, and polio) which once accounted for a substantial proportion of childhood morbidity and mortality has significantly declined since the advent and use of vaccines."); Calandrillo, *supra* note 22 at 353 ("Vaccinations against life-threatening diseases are one of the greatest public health achievements in history. Literally millions of premature deaths have been prevented, and countless more children have been saved from disfiguring illness.").

[101] *See, e.g.,* Calandrillo, *supra* note 22, at 429 ("The AMA has already gone on record indicating its opposition to both religious and philosophical exemptions to vaccination – states might consider doing the same.").

[102] Melinda Wharton et. al., *Concurrent Session: A. Applying Law Throughout the Life Stage: Childhood Immunizations: Exemptions and Vaccine Safety*, 33 J.L. MED. & ETHICS 34 (2005) ("Based on these principles, a nonmedical vaccination exemption has been proposed that requires a firmly held, bonafide belief; proof of health department-approved vaccine counseling; signed personal statement by the parent; *department discretion to reject based on individual and community risk*; annual renewal; and ongoing central exemption tracking" (emphasis added) (citing Daniel A. Salmon et. al., *Public Health and the Politics of School Immunization Requirements*, 95 AM. J. PUB. HEALTH 778 (2005))).

Infantile Paralysis, the non-profit organization that helped develop and distribute the polio vaccine, opposed compulsion on principle.[103]

But fundamental changes in vaccination mandates occurred in the late 1960's. In 1968, half the states had laws requiring one or more vaccinations for school. By 1981, all 50 states had required school vaccines for measles and most other vaccine-preventable childhood diseases.[104]

In the 1960's, mandates served more of a public education role more than a legal one.[105] But state coercion soon became real.

1. The Advisory Committee on Immunization Practices (ACIP)

Although *Jacobson* remained the landmark case on state compulsory vaccination, the federal government began to assume the driving role in immunization policy. Government experts within the Centers for Disease Control and Prevention adopted the goal of eradicating infectious disease.[106] The federal government established an infrastructure for a war on infectious disease. In 1964, the Advisory Committee on Immunization Practices (ACIP) first met.[107] This organization, under the Public Health Service Act,[108] was created to "assist states...in the prevention and control of communicable diseases; to advise states on matters relating to the preservation and improvement of the public's health; and to make grants to states to assist in meeting the costs of communicable disease control programs."[109]

ACIP's charter requires it to advise about vaccines against vaccine-preventable diseases for use by the public.[110] For children, the charter requires ACIP to create a list of vaccines for federal subsidy.[111] ACIP became the only federal entity to make vaccination recommendations

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[103] Colgrove & Bayer, *supra* note 95, at 573 ("Senior managers with the National Foundation for Infantile Paralysis, the charitable organization that was instrumental in developing and distributing the vaccine, believed that compulsory laws were wrong in principle.").

[104] *Id.*

[105] *Id.* ([T]he laws served as a 'means of bringing to individuals' attention to the continuing publicly perceived need for immunization.")

[106] *See, e.g.*, JAMES COLGROVE, STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA 212 (2006) ("In the 1960s, the elusive dream of utterly eliminating one or more infectious diseases came closer to being a reality than ever before, and a spirit of 'eradicationism' took center stage in vaccination policy.... The Communicable Disease Center launched a national campaign to eradicate measles in the fall of 1966.")

[107] CDC: Vaccines Timeline: Fifty Years of Vaccine Progress (Oct. 19, 2006), http://www.cdc.gov/vaccines/pubs/vacc-timeline.htm.

[108] 42 U.S.C.S. § 217a (2010) ("The Secretary may...appoint such advisory councils or committees... for the purpose of advising him in connection with any of his functions."); *see also* ACIP Charter: Authority, Objective, and Description, Authority (Apr. 6, 2010), http://www.cdc.gov/vaccines/recs/acip/ charter.htm.

[109] *Id.* at Objective and Scope of Activities.

[110] *Id.* at Description of Duties. ("provide advice and guidance...regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population")

[111] *Id.*

to the states for public health, and for children in particular.[112] States today rely on ACIP's recommendations for school vaccination mandates. The federal government subsidizes vaccines on the ACIP-recommended list for indigent children,[113] and manufacturers receive liability protection for ACIP-recommended vaccines under the 1986 Law.[114]

ACIP meets several times each year and consists of fifteen non-governmental expert advisors whom the HHS Secretary appoints.[115] In addition to fifteen voting members, ACIP includes eight *ex officio* members who represent federal agencies with responsibility for immunization programs and twenty-six non-voting representatives of liaison organizations.[116] Under its charter, ACIP must have at least one citizen representative -- all the rest may be from public health and medical specialties.[117] In other words, of the forty-nine people charged to deliberate on national vaccine policy, only one must represent the public.

At ACIP's inception, *Jacobson*'s requirements and the federal government's mission for immunization headed in two potentially different directions. *Jacobson* justified state and local health officials to mandate vaccines against contagious epidemics that posed an "imminent danger" to the "entire population."[118] By contrast, ACIP, the new driver of national immunization policy, aimed to prevent and control infectious disease and to fund state childhood vaccination programs with no reference to necessity.[119] ACIP's mission does not reference *Jacobson*'s requirements of emergency, self-defense, imminent danger or local authorities' discretion to fight against disease. Instead, the federal government in ACIP created an infrastructure to prevent and control communicable diseases particularly among children through compulsory vaccination. By 1981, all states made vaccination against most vaccine-preventable diseases mandatory for school attendance.[120]

2. Vaccine Injury Litigation

With more compelled vaccination came more reported vaccine injuries and lawsuits. Plaintiffs brought lawsuits for vaccine injury based on negligence, strict liability and manufacturers' failure to warn of known risks. Although parents did not have the choice to refuse vaccination for children to attend school, except for limited exceptions, they had two tort law protections: the right to accurate warnings and the right to sue manufacturers.

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[112] *Id.* ("establish...review and, as appropriate, revise a list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program....").
[113] *Id.*
[114] 42 U.S.C. 300aa-6 (2010) (authorizing appropriations necessary to carry out the statute's provisions) *and* § 300aa-11 (providing liability protection for manufacturers of vaccines).
[115] ACIP Charter, *supra* note 108, at Meetings, Duration, and Termination: Estimated Number and Frequency of Meetings; *Id.* at Membership, Subcommittees, and Recordkeeping: Membership and Designation.
[116] ACIP Charter, *supra* note 108, at Membership, Subcommittees, and Recordkeeping.
[117] *Id.*
[118] *Jacobson*, 197 U.S. at 29.
[119] ACIP Charter, *supra* note 108, at Authority, Objective, and Description: Objective and Scope of Activities.
[120] COLGROVE, *supra* note 106 at 177.

In two publicized cases, petitioners won lawsuits against vaccine manufacturer Wyeth on failure to warn claims. Both plaintiffs suffered permanent disabilities from the oral polio vaccine. In *Davis v. Wyeth*, an adult contracted polio from the oral polio vaccine and argued in 1968 that he had not been warned of this potential risk.[121] In *Reyes v. Wyeth*, a child contracted polio after receiving the vaccine and argued in 1970 that she had received no warning from the nurse who vaccinated her.[122] The *Reyes* Court rejected the argument that the manufacturer had no duty to warn.[123]

By the 1980's, 250 damage claims against manufacturers for vaccine injury were filed each year.[124] Some vaccine manufacturers left the marketplace and others threatened to do so because of tort liability.[125] Vaccine manufacturers raised the price of vaccines, passing on to consumers the costs of litigation.[126]

In 1965, one year after its inception, ACIP urged the creation of a federal program to compensate victims out of government funds and to relieve manufacturers of ordinary tort liability.[127] ACIP recommended that this would keep the vaccine market stable, keep vaccines affordable and ensure compensation to victims. In part because of the *Davis* and *Reyes* decisions, manufacturers and medical communities joined this recommendation.[128] Later, the American Academy of Pediatrics developed detailed proposals for a compensation scheme that would also relieve doctors of tort liability.[129] And indeed, other developed countries had already adopted governmental compensation schemes for vaccine injury compensation in the 1970's and 1980's.[130]

In another important legal development, scholars and practitioners adopted the Second Restatement of Torts in 1965. As a compilation of tort law and practice, the Second Restatement influenced many state tort laws, particularly in product liability. The Restatement characterized vaccines as "unavoidably unsafe products."[131] The Restatement provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious

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[121] Davis v. Wyeth, 399 F.2d 121 (9th Cir. 1968).
[122] Reyes v. Wyeth, 498 F.2d 1264 (5th Cir. 1974).
[123] *Id.* at 1293; *see* COLGROVE, *supra* note 106, at 189.
[124] COLGROVE, *supra* note 106, at 212.
[125] *Id.* at 190, 213.
[126] *Id.* at 212.
[127] *Id.* at 192.
[128] *Id.* at 193.
[129] *Id.* at 208.
[130] *Id.* at 193.
[131] Restatement (Second) of Torts § 402A cmt. k (1965).

> and damaging consequences when it is injected....Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.[132]

The Restatement noted that a person infected with rabies would likely be willing to accept the risk of an "unavoidably unsafe" vaccine because the alternative was imminent death.[133]

The 1976 swine flu epidemic also played an important role in laying the groundwork for the U.S. compensation scheme that became the 1986 Law. Based on fears of a repeated 1918 flu epidemic, Congress granted vaccine manufacturers liability protection for swine flu vaccines that manufacturers prepared in haste.[134] While the 1976 flu was mild, there were several reports of cardiac arrest and hundreds of cases of a paralytic disorder, Guillain-Barre syndrome, as adverse effects from the vaccines.[135] The program was suspended in 1976 and widely viewed as a failure.[136]

The swine flu episode nonetheless focused public attention on vaccines and the need to provide injury compensation. In 1976-77, the Department of Health, Education and Welfare convened working groups to prepare recommendations. A high profile committee, the Department of Health, Education, and Welfare's committee on informed consent, recommended that voluntary vaccination programs were preferable to mandatory ones.[137] Some advisors, a minority, recommended that "compulsory vaccination was acceptable only in cases where the unvaccinated posed an imminent danger of spreading disease to others."[138] Implicitly drawing on *Jacobson* and John Stuart Mill's utilitarian harm avoidance principle, they argued that people should not be forced to vaccinate simply for their own or the public's good.[139] This group advocated that the national advisory council on vaccination should have a majority or substantial representation of lay citizens.[140]

Despite calls for a compensation system and the swine flu compensation program, the *status quo* of vaccine tort litigation continued through the mid-1980's. A 1982 vaccine injury prompted the Supreme Court of Nevada's 1994 decision, highlighting the problems of lack of informed consent under compulsory vaccination mandates.[141] In *Allison v. Merck*, a mother took

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[132] *Id.*
[133] *Id.*
[134] COLGROVE, *supra* note 106, at 194.
[135] *Id.*
[136] *Id.* at 194-95.
[137] *Id.* at 195-96.
[138] *Id.* at 196.
[139] *Id.*
[140] *Id.* at 197, n.41, citing to "Report and Recommendations, National Immunization Work Group on Consent," in *Reports and Recommendations of the National Immunization Work Groups*, JRB Associates, Mar. 15, 1977 at C 3-4 (A National Immunization Policy Council should have "representatives of the public who are not involved in the production of vaccines or the conduct of the immunization programs. [This group] either should constitute the majority of the Council's membership or should be substantially represented in the membership of the Council.")
[141] Allison v. Merck, 878 P.2d 948 (Nev. 1994).

her seventeen-month old child to receive a measles, mumps and rubella vaccine.[142] The child contracted encephalitis from the vaccine, leading to blindness, deafness, mental retardation and seizures.[143] The Supreme Court of Nevada recognized the mother's right to bring strict liability and failure to warn claims before a jury.[144]

The *Allison* Court disagreed with the Second Restatement of Torts' interpretation of vaccines' "unreasonably dangerous" nature. The Court explained that what frees the manufacturer of the rabies vaccine in *comment k* of the Restatement from liability is not the "unreasonably dangerous" nature of the vaccine, but that the rabies victim *chooses* to be injected with a vaccine known to have "damaging consequences" rather than likely die from rabies.[145] "It is the voluntary choice...that eliminates tort liability," not the "unavoidably unsafe" nature of the product.[146]

The Court pointed out that the mother of the vaccine-injured child "never had any real choice" about vaccinating her son.[147]

> [S]he was faced with the Hobson's choice of either having the vaccine administered or not having the privilege of sending her son to private or public school. Choosing not to have her son attend school, of course, would have subjected her to criminal penalties unless she had the means to have her son educated at home....[I]t is hard to conclude that [the Allisons] freely accepted the risk of the horrible injuries resulting in this case.[148]

The Court found fault with the CDC's warning that accompanied the Merck vaccine and held that a jury could reasonably conclude that the warning was insufficient.[149] It noted that the CDC's warning -- "[a]lthough experts are not sure, there might be a very remote possibility – a chance in a million – that takers of the vaccine may have a more serious reaction, such as inflammation of the brain (encephalitis)"[150] -- did not state that the vaccine could lead to blindness, deafness and mental retardation, as the manufacturer and the government knew were possible.[151] Overturning decisions below, the Court concluded that the petitioners were free to pursue actions for strict liability and duty to warn at trial and remanded the case.[152]

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[142] *Id.* at 951.
[143] *Id.*
[144] *Id.* at 952.
[145] *Id.* at 954.
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *Id.* at 957.
[150] *Id.* (internal quotations omitted).
[151] *Id.* at 958.
[152] *Id.* at 961.

From the 1960's until the 1986 Law took effect, courts decided cases on informed consent and the manufacturer's duty to warn inconsistently, both allowing plaintiffs to put their claims before juries and dismissing their suits before trial.[153] Some cases received big settlements and awards and most received no compensation. In part to address this inconsistency in compensation, Congress passed the 1986 Law.

II. The 1986 Law

Congress enacted the 1986 Law almost two decades after the ACIP first recommended a government compensation scheme. Congress held hearings over many years, including testimony from the pharmaceutical industry, doctors, and parents of vaccine-injured children. Through the Law, Congress sought to achieve several objectives: (1) to create the infrastructure for a national immunization program;[154] (2) to insulate industry and the medical profession from liability;[155] (3) to establish a program to compensate the injured;[156] and (4) to promote safer vaccines.[157]

The Law outlined an ambitious agenda of research, production, procurement, distribution, promotion and purchase of vaccines.[158] It established the National Vaccine Injury Compensation Program (VICP) for "vaccine-related injury or death."[159] In its legislative history, Congress made clear that compensation was to be swift, generous and non-adversarial.[160] Congress enacted the statute to compensate children who were injured while serving the public good.[161]

The Program requires the parents of vaccine-injured children to file first in the VICP before in any other court.[162] The Court of Federal Claims in Washington, D.C. administers it.[163] After filing in the VICP, however, petitioners retain the right to go to civil court after rejecting a VICP decision or waiting a specified period.[164] Congress intended to create an administrative program, where families would establish injuries specified in the Vaccine Injury Table and receive compensation.[165]

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[153] *See, e.g.*, Mazur v. Merck, 964 F.2d 1348 (3rd Cir. 1992) (affirming summary judgment in favor of appellee drug manufacturer).
[154] 42 U.S.C. § 300aa-2.
[155] *Id.* § 300aa-11.
[156] *Id.* § 300aa-10.
[157] *Id.* § 300aa-27.
[158] *Id.* § 300aa-2.
[159] *Id.* § 300aa-10.
[160] Brief of Vaccine Injured Petitioners Bar Association et al. as *Amici Curiae* in Support of Petitioners, Bruesewitz v. Wyeth, Inc., No. 09-152 (filed June 1, 2010) [hereinafter Brief of Vaccine Injured Petitioners Bar Association] (citing H.R. REP. NO. 99-908, pt. 1, *reprinted in* 1986 U.S.C.C.A.N. 6344).
H.R. Rep. 99-908 (1986), reprinted in U.S.C.C.A.N. 6344.
[161] *Id.*
[162] *Id.* § 300aa-11.
[163] *Id.* § 300aa-12.
[164] *Id.* § 300aa-21.
[165] *Id.* § 300aa-14; see current Vaccine Injury Table at http://www.hrsa.gov/vaccinecompensation/table.htm.

When Congress passed the Law, there were many recognized vaccine injuries, including anaphylaxis, encephalopathy, paralytic polio, chronic arthritis, and other acute complications, including death.[166] Almost all injuries on the Vaccine Injury Table were to have occurred within 30 days. Most were to have occurred within hours or days of the vaccine.[167] If petitioners met the precise requirements of the specified injuries, then they would not be required to litigate and would have a presumption of compensation.[168] For injuries that were not listed on the Table, however, petitioners would have to prove them based on a preponderance of the evidence.[169]

The VICP requires that petitioners sue HHS; petitioners cannot sue manufacturers or healthcare practitioners in the Program.[170] HHS is the respondent for all vaccine injury claims in the VICP. The rationale for this protection of industry was to ensure a stable childhood vaccine supply and to keep vaccine prices affordable.[171] The source of VICP compensation is the Vaccine Injury Trust Fund, a fund now containing $3.2 billion collected from an excise tax of $.75 imposed on the sale of every vaccine.[172]

Petitioners try cases in the VICP before Special Masters of the Court of Federal Claims. Eight Special Masters act as finders of fact and law. There are no jury trials.[173] The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.[174] Congress intended this informality to benefit the petitioners and Congress expected that the overwhelming majority of claims would be resolved administratively, where detailed rules of evidence would not be necessary. The statute also requires that the Secretary of HHS "undertake reasonable efforts to inform the public of the availability of the Program."[175]

Petitioners are entitled to receive $250,000 in the event of a vaccine-related death and a maximum amount of $250,000 for pain and suffering.[176] These caps have not changed since 1986. The Act also provides for "reasonable attorney's fees and costs" for bringing a petition so

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[166] *Id.* § 300aa-14.
[167] *Id.*
[168] *Id.*
[169] *Id.* § 300aa-13(a)(1).
[170] *Id.* § 300aa-11(a).
[171] *See, e.g.*, Calandrillo, *supra* note 22, at 408 ("Vaccine manufacturers quickly learned their lesson and threatened to halt production unless guaranteed indemnification by the federal government. As a result, vaccine shortages ensued, prices skyrocketed, and Congress was forced into action.").
[172] Human Resources Services Commission: National Vaccine Injury Compensation Program, Vaccine Injury Compensation Trust Fund, http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm ("The Trust Fund is funded by a $0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine).").
[173] 42 U.S.C. § 300aa-11.
[174] Vaccine Rules of U.S. Fed. Cl., Fed. Cl. R. app. 8(b)(1) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties."), available at http://www.uscfc.uscourts.gov/sites/default/files/Vaccinerules_20100111_v4.pdf.
[175] 42 U.S.C. § 300aa-10.
[176] *Id.* § 300aa-15.

that petitioners do not have to pay lawyers out of pocket or out of the proceeds of a judgment, as they would have to do in civil court under a contingency fee arrangement.[177]

The Law requires that claimants file petitions "no more than 36 months after the first symptom or manifestation of onset or of the significant aggravation of such injury after the administration of the vaccine."[178] This three year statute of limitations is considerably shorter than most state tort statutes for tort injury to minors.

In perhaps the most significant part of the statute, the Law restricts vaccine manufacturers' liability for those vaccines included on ACIP's recommended childhood schedule.[179] Under the Law's terms, starting in 1988, no vaccine manufacturer was liable for a vaccine-related injury or death from one of the ACIP-recommended vaccines "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."[180] Utilizing language from the Second Restatement of Torts, the Law includes this somewhat opaque protection for industry.

The U.S. Supreme Court will hear *Bruesewitz v. Wyeth*, a case interpreting this provision, in October 2010, in part to resolve a split in interpretation between the Supreme Court of Georgia and the Third Circuit Court of Appeals. In 2008, the Supreme Court of Georgia held that civil courts must decide on a case-by-case basis whether a vaccine-related injury is unavoidable for claims of vaccine design defect.[181] By contrast, in 2009, the Third Circuit Court of Appeals held that all vaccine injuries allegedly due to design defect are "unavoidable" under the 1986 Law.[182] The facts of the case from the Third Circuit make up the vignette at the beginning of the article.

In addition to broad liability protection, the Law provides another important protection to manufacturers.[183] Responding to *Reyes v. Wyeth*, the Law provides that vaccine manufacturers are not liable for damages for failure to give direct warnings to those being vaccinated.[184] Resting on the "learned intermediary" doctrine, that it is sufficient to inform doctors of the risks, manufacturers bear no obligation to provide accurate or complete information to those actually vaccinated.[185]

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[177] *Id.*
[178] *Id.* § 300aa-16.
[179] *Id.* § 300aa-22.
[180] *Id.* § 300aa-22(b)(1).
[181] Am. Home Prods. Corp. v. Ferrari, 668 S.E.2d 236 (Ga. 2008).
[182] Bruesewitz v. Wyeth Inc., 561 F.3d 233 (3rd Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).
[183] *Id.* § 300aa-22(c).
[184] *Id.* ("solely due to the manufacturers' failure to provide direct warnings to the injured party of the potential dangers resulting from the administration of the vaccine....")
[185] *Id.*

Complementing manufacturers' relief from disclosure requirements, another provision exempts doctors from substantial disclosure requirements. It tasks the HHS Secretary to "develop and disseminate vaccine information materials."[186] It states that these materials should outline the benefits and risks of vaccines and the availability of the VICP.[187] Doctors are obliged to provide families with these information materials.

Other provisions in the Law establish mandatory procedures in the event that petitioners reject the VICP judgment and bring claims against manufacturers in civil court.[188] These provisions establish that trials must be held in three stages: liability, general damages and punitive damages.[189] Punitive damages may be awarded only in the event of fraud or other criminal or illegal activity relating to the vaccine safety and effectiveness.[190]

Furthering vaccine safety and surveillance, the Law requires certain recordkeeping by healthcare providers and industry.[191] The Law also requires the Secretary of HHS "to promote the development of childhood vaccines that result in fewer and less serious adverse reactions" than those on the market in 1986.[192] And it creates the formal opportunity for citizens' actions against the HHS Secretary to ensure that the Secretary performs her duties. With broad, bipartisan support, the Law took effect in 1987.

III. The Effects of U.S. Vaccine Laws

By law, American children do not have three fundamental protections regarding vaccines: (1) they do not enjoy free choice regarding vaccines if they wish to attend public school (and this is also true for many private schools); (2) they are not entitled to accurate and complete information about the contents and risks of their compulsory vaccines; and (3) they are not entitled to sue vaccine manufacturers in the event of vaccine-induced injury without first filing a claim in the VICP. These deprivations of ordinary tort law protections, created by *Jacobson*, *Zucht* and the 1986 Law, have led to undesirable and unintended consequences. These laws collectively were meant to ensure access to necessary, safe vaccines; meaningful information to parents about vaccines; improvements in overall vaccine safety; and generous and swift compensation in the event of injury. They intended to ensure a framework for rational, unbiased decisions at the federal and state levels for the public health and safety, and especially for children.

But these are not the results in fact. The laws that apply to childhood vaccination mandates in practice permit conflicts of interest; inadequate safety science and surveillance; under-compensation of vaccine-injured children; insufficient warnings about the risks of vaccines; and

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[186] *Id.* § 300aa-26.
[187] *Id.*
[188] *Id.* § 300aa-21.
[189] *Id.* § 300aa-23.
[190] *Id.* § 300aa-23(d).
[191] *Id.* § 300aa-25; *Id.* § 300aa-28.
[192] *Id.* § 300aa-27.

severe sanctions for non-compliance with vaccination mandates. They also may have inadvertently contributed to the poor state of childhood health.

These distorted results arise from tensions in and among these laws. Conflicts in the 1986 Law are apparent at first glance. By locating vaccine promotion, safety and compensation under one umbrella at HHS, Congress created the risk of trade-offs among competing goals. Revenue-generating vaccine development and promotion have enjoyed priority over vaccine safety science and injury compensation since the Law's inception.[193]

The 1986 Law's paradigm of optimal prevention, which differs fundamentally from *Jacobson,* creates additional tensions. Article 1 states that the purpose of the National Vaccine Program is to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention of adverse reactions to vaccines."[194] While building on the premises of *Jacobson* and *Zucht*, the 1986 Law shifts the framework for compulsory vaccination from emergency, necessity and imminent harm to "optimal prevention." The 1986 Law also changes the effective decision makers for vaccine policy. Now, instead of decentralized state legislatures and school boards making almost all vaccination decisions, ACIP, the federal advisory body, wields critical central influence. And ACIP's touchstone is "optimal prevention," not necessity, which has not been legally defined over centuries in the way that "necessity" has been.

Another tension is between the utilitarian goal to serve the majority's health and to compensate for the minority's adverse reactions to vaccines. The 1986 Law for the first time publicly acknowledged that universal compulsory vaccination is likely to cause permanent injury and death to some infants and children. The 1986 Law highlights the troubling issue about whether it is ethical to compel non-emergency, preventive measures on children for school attendance when Congress has acknowledged that these measures are likely to cause injury and death to some. This uncomfortable truth is one that vaccine proponents might prefer to obscure, as discussed below.

The purpose of the 1986 Law was to ensure the safety and reliability of the seven vaccines children then received – polio, diphtheria, pertussis, tetanus, measles, mumps and rubella.[195] But in contrast to that purpose, ACIP now recommends 70 doses of 16 vaccines to children, including vaccines for diseases rarely fatal in the United States, such as varicella and rotavirus, and diseases not contagious through ordinary social contact, such as hepatitis B and

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[193] For instance, after the Gulf oil spill, the Obama Administration proposed separating the Minerals Management Service into two agencies – one responsible for inspecting oil rigs and ensuring safety, and the other responsible for overseeing leases and collecting royalty payments. John M. Broder, *U.S. to Split Up Agency Policing the Oil Industry*, N.Y. TIMES (May 11, 2010), http://www.nytimes.com/2010/05/12/us/12interior.html.

[194] 42 U.S.C. § 300aa-1.

[195] Recommended Schedule for Active Immunization of Normal Infants and Children, 1983 Childhood Immunization Schedule, http://www.cdc.gov/vaccines/pubs/images/schedule1983s.jpg (last visited Aug. 20, 2010).

human papilloma virus.[196] ACIP recommendations are the legal basis for compulsory vaccinations for almost all children in the United States. While states do not generally require all the vaccines that ACIP recommends, state mandates start with the ACIP schedule.

Necessity no longer determines the validity of state childhood vaccination mandates, although *Jacobson* has never been overruled. New vaccine mandates are guided by financial returns on low prevalence diseases, not protection of the entire population against imminent harm.[197] While the 1986 Law's "optimal prevention" language may justify compulsion for low prevalence diseases, *Jacobson*'s requirement for necessity does not.

A. Inadequate Safety

To many knowledgeable critics, the safety of the childhood vaccine program is inadequate. The 1986 Law's removal of ordinary product liability and disclosure requirements arguably created disincentives for industry and medicine to vigorously pursue a safety agenda. Because of *Jacobson*, *Zucht* and the 1986 Law, children lack the ordinary tort law protections of informed consent and the right to sue the manufacturer directly, yet they are compelled to accept medical interventions which are by definition unsafe.

There are several major safety concerns: (1) inadequate testing of vaccines, individually and cumulatively; (2) insufficient attention to vaccine additives; (3) the failure to screen out vulnerable subjects; (4) insufficient incentives and funding for vaccine safety; and (5) government discouragement of discourse about vaccine safety.

Many credible voices in the medical and scientific communities, including Dr. Louis Cooper, a vaccine inventor and the former President of the American Academy of Pediatrics, have acknowledged that vaccine safety is inadequate.[198] With respect to the science purportedly proving no association between vaccines and autism, Dr. Bernadine Healy, the former Director of the National Institutes of Health, has stated simply "the question has not been answered."[199] Dr. Healy has been sharply critical of a medical community unwilling to investigate the tens of

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[196] Recommended Immunization Schedule for Persons Aged 0 Through 6 Years – United States, 2010, http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_0-6yrs-schedule-pr.pdf (last visited Sep. 4, 2010); Recommended Immunization Schedule for Persons Aged 7 Through 18 Years – United States, 2010, http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_7-18yrs-schedule-pr.pdf (last visited Sep. 4, 2010).

[197] Eileen Salinsky & Cole Werble, *The Vaccine Industry: Does It Need a Shot In the Arm?*, NAT'L HEALTH POL'Y FORUM 27-28 (2006), *available at* http://www.nhpf.org/library/background-papers/BP_VaccineIndustry_01-25-06.pdf ("The twin incentives of the VFC [Vaccines For Children] market enhancement and the [tort liability] protections from the National Vaccine Injury Compensation Program have acted to make childhood vaccines very attractive to vaccine companies. Manufacturers are pursuing products for diseases with relatively low prevalence levels and are still securing relatively high prices for the new products.")

[198] Lou Cooper *et al.*, *Protecting Public Trust in Immunization*, 122 PEDIATRICS 149, 152 (2008) at 151.

[199] Interview with Dr. Healy at http://www.cbsnews.com/stories/2008/05/12/cbsnews_investigates/main4086809.shtml.

thousands of children with regressive autism whose parents allege that vaccines contributed to their children's disability.[200]

1. Inadequate Vaccine Testing

While the 1986 Law should ensure robust safety testing of vaccines, it does not. Testing for individual vaccines may be done on small control groups;[201] adverse reactions in clinical trials may be found to be coincidental;[202] safety tests may be designed to achieve desired results rather than actual assessments;[203] and vaccines may not have been evaluated for "carcinogenic, mutagenic potential or impairment of fertility."[204]

There have been almost no scientific studies assessing the safety of the federally-recommended childhood vaccination schedule as a whole, so its overall cost-benefit ratio is unknown. The FDA and CDC test and approve vaccines individually, not as part of the overall vaccination schedule. For example, the federal government recommends that at a baby's two-month doctor visit, the baby receive the Hepatitis B, rotavirus, diphtheria, tetanus, pertussis, Haemophilus influenzae type B, pneumococcal and inactivated poliovirus vaccines simultaneously. In other words, the baby is recommended to receive eight vaccines at once containing a wide array of chemical and biological agents.[205] While a baby receives these vaccines together, the vaccines have not been tested together. At a meeting of the National Vaccine Advisory Committee in 1995, leading government vaccine safety expert Dr. Edward

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[200] *Id*. ("What we're seeing in the bulk of the population: vaccines are safe. But there may be this susceptible group. The fact that there is concern, that you don't want to know that susceptible group is a real disappointment to me. If you know that susceptible group, you can save those children. If you turn your back on the notion that there is a susceptible group...what can I say?")

[201] *See, e.g.* only 143 infants and children (up to age 10) were given the Hepatitis B vaccine before it was federally recommended. They were monitored for 5 days. Merck Recombivax HB, Hepatitis B Vaccine (Recombinant), http://www.merck.com/product/usa/pi_circulars/r/recombivax_ hb/recombivax_pi.pdf.

[202] *See, e.g.,* Sanofi Pasteur Poliovirus Vaccine Inactivated IPOL,http://www.fda.gov/downloads/biologicsblood vaccines/vaccines/approvedproducts/ucm133479.pdf ("Although no causal relationship has been established, deaths have occurred in temporal association after...IPV.").

[203] *See, e.g.,* in Merck's placebo-controlled tests before gaining approval of the Gardasil vaccine, it used a solution containing 225 mcg of aluminum as its placebo rather than a typical placebo of water or saline. Merck Highlights of Prescribing Information, http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf; *see also* Blaxill, *infra* note 251.

[204] *See, e.g.*, Merck & Co. Inc., M-M-R II (Measles, Mumps, and Rubella Virus Vaccine Live), http://www.fda.gov/ downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf (last visited Aug. 16, 2010) (noting that the vaccines had "not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility"); *see also* Sanofi Pasteur, Diphtheria and Tetanus Toxoids and Acellular Pertussis Absorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate Vaccine) Pentacel, http://www.doh.state.fl.us/disease_ctrl/immune/files/Pentacel-VS-20Jun08.pdf (noting that no studies had been performed to "evaluate carcinogenicity, mutagenic potential, or impairment of fertility").

[205] *Recommended Immunization Schedule for Persons Aged 0 Through 18 Years --- United States, 2010,* MORBIDITY & MORTALITY WKLY R. (2007), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5851a6.htm?s_cid=mm5851a6_e.

Marcuse acknowledged that "no medical studies exist which prove the safety of this practice [combining multiple vaccines, such as measles, mumps and rubella]."[206]

2. Dangerous Vaccine Additives

Vaccines today contain many known toxic substances. In addition to the pathogenic agents that trigger intended immune responses, vaccines contain preservatives to retain potency and adjuvants to boost immune response. These added ingredients permit smaller amounts of antigen and fewer vaccine doses to achieve documented immunity. Supplemental vaccine ingredients in a variety of vaccines include aluminum hydroxide, formaldehyde, thimerosal (mercury), bovine extract, ammonium sulfate, mouse serum protein, MSG, monkey kidney tissue, egg albumin, lactose, glucose and casein, to name a few.[207] Simian Virus 40, inadvertently contained in intramuscular polio vaccines, has been associated with several different human cancers, including mesotheliomas and brain cancers.[208]

Certain vaccine ingredients used as preservatives and adjuvants, such as aluminum and mercury, are recognized neurotoxins.[209] The amount of mercury used in most mandated vaccines throughout the 1990's and in most seasonal flu vaccines today is 25 micrograms or 25,000 parts per billion – over 100 times the 200 parts per billion classification the Environmental Protection Agency sets for hazardous waste.[210] On mercury's long-time use as a vaccine preservative, Dr. George Lucier, former Director of the National Toxicology Program of the National Institute of Environmental Health Sciences, wrote:

> I conclude that the justification for considering thimerosal or merthiolate as safe was inadequate and flawed, information on alternative preservatives was ignored, the vaccine manufacturers ignored a significant body of knowledge on health

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[206] Kristine Severyn, Jacobson v. Massachusetts: *Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & L. 249, 269, n. 141 (1995-1996) (reporting statement of Dr. Edward Marcuse, chair of the National Vaccine Advisory Committee, at Mar. 1, 1995 meeting of the Advisory Commission on Childhood Vaccines (Transcript available from: Advisory Commission on Childhood Vaccines, Division of Vaccine Injury Compensation, U.S. Public Health Service, Parklawn Building, Room 8a-35, 5600 Fishers Lane, Rockville, Maryland 20857)).

[207] CDC Vaccine Excipient & Media Summary, Part 2: Excipients Included in U.S. Vaccines, By Vaccine (March 2010), http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf.

[208] DEBBIE BOOKCHIN & JIM SCHUMACHER, THE VIRUS AND THE VACCINE: CONTAMINATED VACCINE, DEADLY CANCERS, AND GOVERNMENT NEGLECT 215 (2004) (noting that studies describing an association between Simian Virus 40 and human cancers, including mesotheliomas, brain and bone cancers have been published).

[209] For neurotoxic effects of mercury, *see* U.S. Environmental Protection Agency at http://www.epa.gov/mercury/health.htm, and for aluminum, *see* National Center for Biotechnology Information at http://www.ncbi.nlm.nih.gov/pubmed/2198876.

[210] EPA National Primary Drinking Water Regulations, http://www.epa.gov/ogwdw000/consumer/pdf/mcl.pdf; *see also* FDA Vaccines, Blood, & Biologics, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228.

effects for at least 50 years and that the vaccine manufacturers did not conduct necessary toxicology studies to establish safety.[211]

3. Failure to Screen Vulnerable Subjects

One of the 1986 Law's objectives is to prevent adverse vaccine reactions. But this objective has not been vigorously pursued. Little effort has been made to preemptively screen out those most likely to be injured by vaccination. As one vaccine safety advocate said:

> The fact that there has been no attention paid by industry and government to minimizing vaccine risks, including no scientific research – as the Act called for – into identifying individuals at high risk for suffering vaccine adverse responses so their lives can be spared – speaks volumes about the disconnect between the intent of Congress to prevent vaccine injuries and deaths and the intent of those operating the federal compensation system to deny they exist.[212]

A long list of medical injuries has been proven to be more likely than not due to vaccines in the VICP. These proceedings rest almost exclusively on peer-reviewed science and medical testimony, requiring the same standards for evidence as in civil proceedings, although the federal rules of evidence do not apply formally.[213] In these proceedings, the Court of Federal Claims has concluded that many medical injuries were due to vaccines, including optic neuritis, acute-disseminated encephalomyelitis, multiple sclerosis, Guillain-Barre Syndrome, transverse myelitis, seizure disorder, chronic inflammatory demyelinating polyneuropathy, scarring, hemolytic anemia, familial hemophagocytic lymphohistiocytosis (an inherited immune deficiency), attention deficit disorder, learning disabilities, behavioral problems, mental retardation in a child who became autistic, pervasive developmental delay, and death.[214] Presumably these cases could be studied for use in devising screening models of what kinds of children are at highest risk of injury, but this is not being done.

4. Insufficient Incentives and Funding for Vaccine Safety

The 1986 Law states vaccine safety as one of its objectives. But this objective remains unfulfilled. The hearings preceding the 1986 Law looked at whether liability protection for industry might diminish its incentives to achieve vaccine safety. In testifying before Congress, Dr. Jonas Salk, one of the inventors of the polio vaccine, favored the 1986 Law but expressed

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[211] George Lucier, "Thimerosol is a Developmental Neurotoxicant," report available at http://www.vtce.org/mercury/ lucier.pdf.

[212] Barbara Loe Fisher, Co-Founder and President, Nat'l Vaccine Info. Ctr., Statement to Advisory Comm'n on Childhood Vaccines: The Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform? (Nov. 18, 2008), http://www.nvic.org/injury-compensation/vaccineinjury.aspx.

[213] Vaccine Rules of U.S. Fed. Cl., Fed. Cl. R. app. 8(b)(1), *supra* note 174.

[214] Brief for Petitioner-Appellant at 21-24, Cedillo v. Sec'y of Health & Human Servs., No. 2010-5004 (Fed. Cir. Jan. 19, 2010).

concern that it might "remov[e]...the incentive for manufacturers and the scientific community to improve existing vaccines."[215]

Dr. Robert Chen, Chief, Vaccine Safety and Development of the CDC, acknowledged this problem again in 1995 when he said "in theory at least one might say that, by creating a no-fault compensation system, it takes a bit more of the pressure off of the manufacturers and may reduce the incentive at least in the private sector for vaccine safety research."[216] Dr. Chen made clear in the same presentation, though, that the pursuit of vaccine safety science within the government was not much better: "the only line item for vaccine safety research is I think on the order of a little less than $2 million per year. That basically covers basic operation of VAERS [Vaccine Adverse Event Reporting System], period, and nothing else. Everything else has been begged, borrowed and stolen."[217]

According to Dr. Chen's testimony, in 1995, vaccine safety was .2% of the total vaccine budget of about $1 billion.[218] Today, the situation is not significantly different. In a 2008 article in *Pediatrics*, Dr. Louis Cooper, vaccine inventor and former President of the American Academy of Pediatrics, lamented that the vaccine safety science budget was $20 million out of a total vaccine budget for purchase, promotion and delivery of $4 billion, or .5%.[219]

Liability protection for industry and insufficient safety science funding have not served the interests of children's safety.

5. Government Discouragement of Public Discourse on Vaccine Safety

Secretary of Health and Human Services Sebelius recently acknowledged that HHS requested the media not to report on critics of vaccine safety during the H1N1 swine flu epidemic.[220] She said in a magazine interview, "We have reached out to media outlets to try to get them to not give the views of these people [vaccine safety critics] equal weight in their reporting to what science has shown and continues to show about the safety of vaccines."[221] Failure to report criticism of vaccine safety is unlikely to resolve the serious questions that surround it.

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[215] *Id.* at 262.

[216] *Id.* n. 97 (citing Advisory Commission on Childhood Vaccines (ACCV) and National Vaccine Advisory Committee (NVAC) Subcommittees on Vaccine Safety, May 31, 1995, Parklawn Building, Conference Room D, Rockville, Maryland, at 75. Transcript available from Division of Vaccine Injury Compensation, Parklawn Building, Room 8A-35, 5600 Fishers Lane, Rockville, Maryland 20857).

[217] *Id.* at 270, n. 142.

[218] *Id.*

[219] Cooper *et al.*, *supra* note 198.

[220] Arthur Allen, *H1N1: The Report Card*, READER'S DIGEST (Mar. 2009), http://www.rd.com/health-slideshows/h1n1-the-report-card/article174741-1.html (interview with HHS Secretary Sebelius).

[221] *Id.*

B. Failure to Compensate Vaccine Injury Victims Generously

The 1986 Law requires that the VICP compensate vaccine-injured children generously. The VICP has failed in this responsibility. The legislative history of the Law shows that Congress saw the VICP as a way to maintain the public trust in vaccines and to honor the social compact. To compensate an injured family is similar to taking care of war veterans – the society is providing for those who suffered for the collective good. Congress intended the VICP to ensure that society supports the individual families who bear the brunt of "unavoidably unsafe" compulsory vaccines.

There is another way to view vaccine injury compensation, however, and that is to see it as undermining the public message that "vaccines are safe and effective." According to this second view, acknowledging injury is potentially dangerous, undermining the public narrative of overwhelming vaccine safety. HHS and DOJ actions suggest that they view vaccine injury compensation in the second way, seeing awards as undermining the public trust in a universal vaccine program.

In the early 1990's, just a few years after the 1986 Law took effect, HHS used its discretionary authority to eliminate almost all on-Table adverse events creating presumptions for recovery.[222] These actions were despite the purpose of the VICP to provide a presumptive, no-fault administrative remedy. HHS Secretary Shalala removed "residual seizure disorder" from the Table of Vaccine Injury, nullifying the presumptive compensation category for children who suffered seizures immediately after the DPT vaccine. As a result, almost all DPT seizure disorder cases became off-Table, requiring litigation. Those cases met with varying results.[223] HHS also redefined "encephalopathy," a recognized compensable injury, to exclude almost all cases from on-Table compensation.[224] Despite Congress' intent that the VICP be an administrative program, today almost all cases must be litigated to establish causation.

Vaccine-injured petitioners challenged and appealed these HHS administrative changes to the First Circuit Court of Appeals, which upheld HHS' administrative actions.[225] These changes altered the character of the VICP fundamentally. According to Barbara Loe Fisher, a leading vaccine safety advocate, these HHS actions "turned the administrative compensation

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[222] 60 Fed. Reg. 7678 (Feb. 8, 1995).

[223] *See* Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367 (Fed. Cir. 2009) (allowing compensation for seizures caused by DPT vaccine); *but see* Bruesewitz v. Sec'y of Health & Human Servs., 2002 U.S. Claims LEXIS 364 (Fed. Cl. 2002) (denying compensation for seizure disorder allegedly caused by DPT vaccine).

[224] "Proposed Changes to the Vaccine Injury Table," HHS memo dated Aug. 21, 1992, at http://www.hhs.gov/news/press/pre1995pres/920821.txt.

[225] O'Connell v. Shalala, 79 F.3d 170 (1st Cir. 1996) (holding that the Secretary of Health and Human Services had the power to promulgate a rule removing residual seizure disorder from the vaccine injury table and changing the definition of encephalopathy). The petitioners also brought an appellate suit in the Court of Federal Claims after they were denied compensation, but because they rested their arguments on the same constitutional grounds they used in the First Circuit case, the Court held that the suit was barred by *res judicata*. O'Connell v. Sec'y of Health & Human Servs., 1999 U.S. App. LEXIS 28427 (1999), *cert. denied*, 531 U.S. 812 (2000).

process into a highly adversarial, lengthy, expensive, traumatic and unfair imitation of a court trial for vaccine victims and their attorneys."[226]

The failure to add new presumptions for recovery is another indicator of HHS' disinclination to grant compensation. Despite the fact that nine new vaccines have been added to the ACIP childhood vaccine schedule since 1986, more than doubling the possibility of vaccine injury, only one new Table injury has been added – anaphylaxis within 4 hours of the hepatitis B vaccine.[227]

The former Chief Special Master, Gary Golkiewicz, acknowledged the Program's bias against petitioners.[228] After HHS administrative changes to the Program in 1998, he is quoted in a recent book on vaccines as having said:

> [the government] altered the game so that it's clearly in their favor. This group [HHS and DOJ] has a vested interest in vaccines being good. It doesn't take a mental giant to see the fundamental unfairness in this.[229]

In a later speech to the Advisory Commission on Childhood Vaccines, Special Master Golkiewicz again acknowledged the conflict between compensation and what he called "vaccine's integrity," or the possibility that injuries occurring shortly after vaccination might be unrelated to vaccines. He acknowledged that "there's a tension between these two objectives [to compensate and to protect the "vaccine's integrity"], a tension that affects dramatically the litigation of the cases, the parties' arguments and ultimately who wins."[230] He acknowledged the conflict HHS perceives.

Since its creation, the VICP has compensated nearly 2,500 victims of vaccine injury and has dispensed over $2 billion in damages.[231] But more than 4 out of 5 claimants have not received compensation.[232] In what Congress intended to be a non-adversarial forum to provide generous administrative compensation, it is striking that over 80% of claims have gone uncompensated.

Although the 1986 Law requires "reasonable efforts" to inform the public about the existence of the VICP, the total budget for publicizing the program is $10,000.[233] The total

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[226] Fisher, *supra* note 212.
[227] Vaccine Injury Table, *supra* note 165.
[228] ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER 293 (2007).
[229] *Id.*
[230] Chief Special Master Gary Golkiewicz, Presentation to the Advisory Commission on Childhood Vaccines (Mar. 6-7, 2008) *available at* http://www.hrsa.gov/vaccinecompensation/GolkewiczTranscript.htm.
[231] National Vaccine Injury Compensation Program, *supra* note 4.
[232] *Id.*
[233] Comments of Dr. Geoffrey Evans, Transcript at 46, Dept. of Health and Human Servs., Advisory Commission on Childhood Vaccines (June 5, 2009), http://www.hrsa.gov/vaccinecompensation/Docs/Transcript_ACCV-6-5-09.pdf.

amount of compensation the VICP awards depends in part on the number of people aware of the VICP who file timely claims. The $4 billion budget for vaccine promotion and development dwarfs this outreach budget and at least raises the question whether HHS is taking "reasonable efforts" in good faith to let the public know about the availability of compensation for vaccine injury.

Due to several factors, one can reasonably infer that the VICP has compensated fewer cases than the actual number of vaccine injury cases since the Law has been in effect. These factors include ignorance about vaccine injury; ignorance about the compensation program; a three-year statute of limitations; an adversarial litigation context; inconsistent judgments by Special Masters; VICP's deterrence of experienced lawyers and medical experts through delayed and below-market compensation; and unavailability of medical documentation to prevail on claims. The VICP has failed to compensate generously, despite Congress' intent.

C. Failure to Provide Accurate Information

The norm of informed consent in medicine requires doctors to provide extensive information about the known risks of interventions to patients and to allow the patients to make the ultimate decisions about medical interventions and treatments.[234] Similarly, drug manufacturers are in general required by law to provide accurate and complete information about drug risks with their products. Under *Jacobson*, *Zucht* and the 1986 Law, however, these norms do not apply to compulsory vaccines for children. The 1986 Law does not require doctors or vaccine manufacturers to give complete warnings directly to the person or guardian of the child being vaccinated. It requires that doctors give government-produced 'information materials' and requires that manufacturers provide proper warnings to doctors only, who are considered to be "learned intermediaries."[235] Both industry and the medical community lobbied for this lowered information standard after *Reyes v. Wyeth*.[236]

The 1986 Law initially required more information than what parents receive today. The 1986 Law specified ten items for Vaccine Information Materials (VIMs) to cover.[237] The initial versions were 12 pages long and required parental signature. But pediatricians found the brochures were "scaring" parents and took too much time.[238] The American Academy of

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[234] *See, e.g.*, 61 AM. JUR. 2D *Physicians, Surgeons, Etc.* § 175 (2010) ("The doctrine of informed consent imposes on a physician the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in all collateral therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo the treatment.").

[235] *See, e.g.*, 28 C.J.S. *Drugs and Narcotics* § 128 (2010) ("Under the learned-intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient, consumer or general public of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.").

[236] Reyes v. Wyeth, *supra* notes 122 to 130 and accompanying text.

[237] *See* Severyn, *supra* note 206, at 270 (citing 42 U.S.C. § 300aa-26(c) (1986)).

[238] *Id.* at 270-271.

Pediatrics submitted legislation to shorten the VIMs. Congress enacted the proposed changes in 1993. Instead of ten information items, statements for parents now contained four: the benefits of the vaccine, the risks, one sentence about the VICP and a reference to the CDC for further information. Parents' signatures were also eliminated in this change. In an advisory to doctors, the CDC wrote that the new VIMs "provide enough information that anyone reading the materials should be adequately informed."[239]

The current Measles, Mumps and Rubella VIM states under its heading of "Severe Problems (Very Rare)":

> Serious allergic reaction (less than 1 out of a million doses). Several other severe problems have been known to occur after a child gets MMR vaccine *(sic)*. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include: deafness, long-term seizures, coma or lowered consciousness, permanent brain damage.[240]

That "experts cannot be sure whether they are caused by the vaccine or not" is inaccurate. The VICP has compensated 301 cases of MMR-induced vaccine injury under the standard of more likely than not.[241] This VIM inaccurately describes the risk of vaccine injury. The *Allison v. Merck* court described above likely would have found this warning improper under the pre-1986 Law standards, but it suffices under the 1986 Law.

The amended 1986 Law deprives parents of thorough information about vaccines. And in addition to parental ignorance about vaccine adverse reactions, some doctors may lack knowledge, dismissing medical problems after vaccines as coincidental.[242] Vulnerable children may be at higher risk of suffering adverse vaccine reactions than necessary because of inadequate knowledge, both among parents and doctors. The 1986 Law has facilitated this possibility.

D. Conflicts of Interest and Troubling Aspects of the Vaccine Industry

1. Conflicts of Interest

Part of *Jacobson*'s rationale for deference to state legislatures was their representative nature; legislatures by their nature are required to take account of differing views in the population. Indeed, if the legislature makes bad choices, the electorate can reverse those choices

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[239] *Id.* at 272 (citing Preventative Health Amendments of 1993 tit. VII, 708, H.R. 2202, 103d Cong., 1st Sess., Vaccine Information Materials: Questions and Answers, at 8Q (1993)(included in mailing to Ohio physicians)).
[240] Measles, Mumps, & Rubella (MMR) Vaccines: What You Need To Know (Mar. 13, 2008), http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-mmr.pdf.
[241] National Vaccine Injury Compensation Program, *supra* note 4 (reporting that the National Vaccine Injury Compensation Program has compensated 2,472 total claims, with 301 of them being related to MMR vaccine).
[242] Fisher, *supra* note 212.

and unseat the legislators through popular elections. But ACIP is now the driving force behind vaccination mandates, a federal advisory body with little public participation and no direct accountability to voters. Because of this change in the locus of decision-making from legislators to ACIP, codified by the 1986 Law, there are perhaps greater risks of conflicts of interest. Many ACIP advisors have ties to industry and their views and judgments may be motivated more by financial and professional self-interest than by protecting the public health.

In 2000, a Congressional report on "Conflicts of Interest in Vaccine Policy Making," identified pervasive conflicts of interest in the FDA and CDC advisory bodies that make national vaccine policy.[243] The report looked in detail at the conflict of interests in the decision making that led the FDA and CDC to approve Merck's Rotashield vaccine against rotavirus, an intestinal disease of infants.[244] Merck voluntarily withdrew Rotashield from the market thirteen months after launch due to serious adverse reactions.[245] The House Government Reform Committee found numerous problems with the approval of Rotashield and with vaccine approvals in general:

- advisers' financial ties to vaccine manufacturers;
- little unbiased public participation;
- insufficient use of conflict of interest waivers;
- advisers' permitted stock ownership in companies affected by their decisions;
- advisers' lack of disclosure of partisan expert witness work;
- advisers who held vaccine patents approving vaccines for the same disease;
- excessively long terms for committee members; and
- liaison members' undisclosed ties to vaccine manufacturers.[246]

There is little evidence that the CDC or FDA implemented the report's recommendations. In 2008, eight years later, an Office of Inspector General of HHS study of disclosure and conflict waivers found that 97% of Special Government Advisers on committees at the CDC failed to disclose necessary information about conflicts of interest,[247] prompting criminal investigation of some.[248]

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[243] STAFF OF H. GOV. REFORM COMM., 106TH CONG., CONFLICTS OF INTEREST IN VACCINE POLICY MAKING 41 (Comm. Print 4024), http://www.nvic.org/nvic-archives/conflicts-of-interest.aspx ("In the interest of public health, Congress should revise existing law to ensure that advisory committees contributing to vaccine policymaking are not unduly affected by individuals with conflicts of interest.").

[244] *Id.* at 8.

[245] *Id.* at 9.

[246] *Id.* at 2.

[247] DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GEN., OEI-04-07-00260, CDC'S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES (2009).

[248] *Id.* at 23 n. 69 ("The cases were forwarded to the OIG Office of Investigations because the waivers were created pursuant to the criminal conflict-of-interest statute. The OIG Office of Investigations reviewed information regarding these seven SGEs [special government employees] and determined, largely as a result of CDC's systemic lack of oversight of the ethics program for SGEs identified in this report, that the actions of the seven SGEs did not rise to the level of criminal violations of the conflict-of-interest statute.").

Illustrative of the culture of conflicts of interest is the former Director of the CDC, Dr. Julie Gerberding. One year after she left the CDC as Director, she joined Merck as the President of its Vaccine Group.[249] During her tenure at CDC, ACIP approved Merck's Gardasil vaccine for human papilloma virus against cervical cancer.[250] Gardasil is the most expensive vaccine for the least prevalent disease that ACIP has ever approved and recommended for universal use. There were well-documented conflicts of interest in the Gardasil approval process. Since ACIP's approval in 2007, there have been allegations of severe injury and death from the vaccine.[251]

While conflicts of interest in vaccine mandates were identified as a problem at least as early as 1911,[252] what is new is the potential scale of damage from such conflicts. Because all school children in the country are now subject to 30-45 compulsory vaccines recommended by ACIP, conflicts of interests may have potentially greater impact than when vaccination mandates were solely state and local matters. The 1986 Law, which centralized national vaccination policy and created its infrastructure, facilitated rather than minimized potential conflicts of interest

2. The Pharmaceutical Industry

From the 1980's through the early 2000's, the pharmaceutical industry, which produces vaccines, was the most profitable industry in the United States. In 2002, the combined profits of the ten largest drug companies in the Fortune 500 had higher net profits, of $35.9 billion, than all the other 490 companies combined, which had net profits of $33.7 billion.[253] Also in 2002, the pharmaceutical industry employed 675 full-time lobbyists in Washington, more than the number of people in both Houses of Congress.[254] It spent $91 million annually for lobbying.[255] In addition to direct lobbying, the industry funded indirect forms of marketing to promote its agenda. It funded research, continuing medical education for doctors and health advocacy

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[249] Dr. Julie Gerberding Named President of Merck Vaccines (Dec. 21, 2009), https://merck.com/newsroom/news-release-archive/corporate/2009_1221.html.

[250] *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MORBIDITY & MORTALITY WKLY R. (2007), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm.

[251] Mark Blaxill, A License to Kill? Part 1: How A Public-Private Partnership Made the Government Merck's Gardasil Partner (May 12, 2010), http://www.ageofautism.com/2010/05/a-license-to-kill-part-1-how-a-publicprivate-partnership-made-the-government-mercks-gardasil-partner.html; *see also* Mark Blaxill, A License to Kill? Part 2: Who Guards Gardasil's Guardians? (May 12, 2010), http://www.ageofautism.com/2010/05/a-license-to-kill-part-2-who-guards-gardasils-guardians.html; Mark Blaxill, A License to Kill? Part 3: After Gardasil's Launch, More Victims, More Bad Safety Analysis and a Revolving Door Culture (May 13, 2010), http://www.ageofautism.com/2010/05/a-license-to-kill-part-3-after-gardasils-launch-more-victims-more-bad-safety-analysis-and-a-revolvin.html *and* The Truth About Gardasil, http://truthaboutgardasil.org (alleging that thousands of girls suffered adverse reactions to Gardasil, including 71 deaths).

[252] See *supra* notes 66 to 70, discussing Rhea v. Bd. of Educ.

[253] MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 11 (2005).

[254] *Id.* at 198.

[255] *Id.*

groups,[256] such as the Immunization Action Coalition,[257] that appear to advance an impartial health agenda but in fact serve as pharmaceutical marketing agents.

A handful of pharmaceutical corporations dominate the vaccine market, and there are high barriers to entry. Although there were over 30 vaccine manufacturers in the 1960's, today just four corporations produce almost the entire U.S. vaccine supply: Merck, Pfizer (which recently acquired Wyeth), GlaxoSmithKline and Sanofi Pasteur.[258] These companies manufacture almost 80 percent of the global vaccine market as well.[259] Furthermore, these four suppliers have one primary customer in the U.S.: the federal government. The U.S. government purchases almost 60 percent of all vaccines in country.[260] The corporations have close relations with HHS, which oversees the agencies that regulate and interface with these industries.

Although the vaccine market is a small part of the overall pharmaceutical market, at around 1.5 percent,[261] it now has high margins and is expanding with double digit growth.[262] Vaccine manufacture for the children's market is a high margin, low risk business. Indeed, global sales of vaccines reached $22.1 billion in 2009, up 16% from the previous year.[263] And industry plans to capitalize on vaccines in the near term, predicting nearly ten percent annual growth of the market over the next five years, pushing sales to roughly $35 billion.[264] Many "blockbuster" drugs like Lipitor, Plavix and Singulair are going off patent, perhaps leading drug manufacturers to look to children's compulsory and recommended vaccines to make up revenue shortfalls.

In a system this oligarchic, corruption is a concern. But in the vaccine market, these concerns should be heightened. Because children have abrogated rights to informed consent and the right to sue under *Jacobson*, *Zucht* and the1986 Law, they have relatively few legal rights of redress. It is particularly troubling that the primary childhood vaccine manufacturers, Pfizer, Merck and GlaxoSmithKline, have records of fraud and criminal or ethical misconduct in marketing other drugs where they face ordinary tort liability that they do not face by law in the vaccine market.

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[256] *Id.* at 138.

[257] IAC Funding, Immunization Action Coalition, http://www.immunize.org/aboutus/funding.asp (listing seven drug companies that donated money in 2010).

[258] The Vaccine Industry – An Overview (July 2010), http://www.vaccineethics.org/issue_briefs/industry.php.

[259] *Id.*

[260] *Id.*

[261] *Id.*

[262] *See* Salinsky & Werble, *supra* note 197, at 12.

[263] Linda A. Johnson, Vaccine sales up 16 pct in 2009, still growing, *Associated Press*, Aug. 13, 2010 *available at* http://www.wgal.com/r/24620886/detail.html.

[264] *Id.*; *see also* Andrew Barry, *Wonder Drugs*, BARRON'S, June 28, 2010, http://online.barrons.com/article/SB500014240529 70203296004575320891909686872.html#articleTabs_panel_article%3D1.

In 2009, Pfizer entered into the largest criminal settlement in U.S. history. It paid a $1.2 billion as a criminal penalty, plus additional fines of over $1 billion.[265] The corporation acknowledged having made false and misleading claims about the safety and effectiveness of its drugs and promoting off-label, illegal uses. It was a repeat offender, having been charged with four such violations since 2002.[266] The FBI lauded the whistleblowers that came forward to stop the corporation from "blatantly violating the law and misleading the public through false marketing claims."[267] Pfizer, through its recent purchase of Wyeth, makes one vaccine among ACIP-recommended vaccines.[268]

Merck voluntarily withdrew its anti-inflammatory drug Vioxx from the market in 2004.[269] Congressional hearings at that time suggested that up to 55,600 people probably died as a result of heart attacks and strokes directly linked to Vioxx's failure to alert users to contraindications and possible adverse events.[270] The Congressional hearings suggested that Merck knew of the likelihood of these side effects in 1998, before the FDA approved the drug in 1999.[271] The approval process suggested conflicts of interest.[272] To compensate victims, Merck entered into a settlement to pay $4.85 billion to nearly 50,000 eligible claimants.[273] Merck manufactures ten vaccines that are among ACIP-recommended vaccines.[274]

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[265] Settlement Agreement, 2009, http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/Pfizer%20Settlement%20Agreement.pdf; *see also* Pfizer Concludes Previously Disclosed Settlement Agreement With U.S. Department Of Justice Regarding Past Promotional Practices: Company Reaches Settlement with States on Related Matter, BUSINESS WIRE, Sep. 2, 2009, http://www.businesswire.com/portal/site/home/permalink/ndmViewId=news_view&newsId=20090902005690&newsLang=en. (last visited Sept. 4, 2010).

[266] *See Pfizer to Pay Record $2.3 Billion Penalty*, ASSOCIATED PRESS (Sep. 2, 2009), http://www.msnbc.msn.com/id/ 32657347/.

[267] *Id.*

[268] Complete List of Vaccines Licensed for Immunization and Distribution in the US, FDA Vaccines, Blood, and Biologics (June 3, 2010), http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm [hereinafter Complete List of Vaccines] (listing Wyeth as the manufacturer of pneumococcal vaccine).

[269] Merck News Release: Merck Announces Voluntary Worldwide Withdrawal of Vioxx, Sep. 30, 2004, https://merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf.

[270] Reporting on Congress's findings during its Vioxx hearings, reporter Susan Dentzer stated, "Graham [an FDA safety officer whistleblower] then offered an estimate of the scope of the debacle in terms of the number of Americans who took Vioxx and then experienced additional heart attacks and strokes." Dr. David Graham clarified, "This estimate ranges from 88,000 to 139,000 Americans. Of these, 30 to 40 percent probably died." Susan Dentzer et al., Drug Failure, Online NewsHour (Nov. 18, 2004), http://www.pbs.org/newshour/bb/health/july-dec04/vioxx_11-18.html.

[271] *Id.*

[272] Vale Krenik, Note and Comment, *"No One Can Serve Two Masters:" A Separation of Powers Solution for Conflicts of Interest Within the Department of Health and Human Services*, 12 TEX. WESLEYAN L. REV. 585 (Spring 2006).

[273] Vioxx Settlement Almost Wrapped Up, NewsInferno, Mar. 2, 2010, http://www.newsinferno.com/archives/18957 ("To settle most of those suits, Merck established a $4.85 billion fund in November 2007. Merck set up a $4 billion fund for people who claim they suffered heart attacks as a result of Vioxx, and another $850 million fund for those who suffered ischemic strokes.").

[274] Complete List of Vaccines, *supra* note 268 (noting that Merck manufactures vaccines for haemophilus B, hepatitis A, hepatitis B, human papillomavirus, measles, mumps, rubella, pneumococcal, rotavirus, and varicella).

In 2010, a Congressional hearing suggested that GlaxoKlineSmith failed to warn the FDA about the potentially serious side effects of Avandia, its diabetes drug.[275] An independent review of the clinical trial record "found a dozen instances in which patients taking Avandia appeared to suffer serious heart problems that were not counted in the study's tally of adverse events."[276] The failure of the FDA approval system to uncover these undisclosed adverse events prompted Dr. Jerome Kassirer, former Editor in Chief of the *New England Journal of Medicine*, to ask "whether the entire system is corrupt."[277] Glaxo manufactures nine ACIP-recommended vaccines.[278]

Certain reports and industry actions raise direct concerns about unethical actions in the area of childhood vaccines. For example, a memo obtained from Merck in civil discovery showed that the director of Merck's vaccine division was concerned about the risks of cumulative infant mercury exposure from vaccines in 1991, eight years before the federal government required initial removal of mercury from vaccines.[279] Another industry memo allegedly given by a whistleblower to a reporter and available on the internet, showed that Wyeth executives instructed vaccine lots to be sold around the country, and not in any concentrated area, to avoid any appearance that vaccines might cause Sudden Infant Death Syndrome.[280] And regarding thimerosal, the mercury-containing vaccine preservative, Congress voted to reverse the "Lilly rider" to the Homeland Security Act of 2002, an anonymous rider attached to the Act to grant the Eli Lily corporation blanket immunity from any side effects that may have resulted from thimerosal's past use in childhood vaccines.[281]

Due in part to the absence of ordinary tort law protections, the vaccine marketplace is uniquely favorable to industry. Logically, demonstrably predatory corporations selling compulsory products to a vulnerable population should lead to a high level of government scrutiny and skepticism. But this is not apparent. On the contrary, government appears to ally its interests with industry in the arena of vaccines. Examples of the government's allegiance are

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[275] Darla Miles, *Senate Report: Avandia Maker Knew of Cardiac Risks*, ABC EYEWITNESS NEWS, Feb. 20, 2010, http://abclocal.go.com/ wabc/story?section=news/health&id=7288680.

[276] Gardiner Harris, *Caustic Government Report Deals Blow to Diabetes Drug*, N.Y. TIMES, July 9, 2010, http://www.nytimes.com/2010/07/10/health/10diabetes.html.

[277] *Id.*

[278] Complete List of Vaccines, *supra* note 268 (noting that GlaxoKlineSmith manufacturers vaccines for diphtheria, tetanus, pertussis, haemophilus B, hepatitis A, hepatitis B, human papillomavirus, influenza, and rotavirus).

[279] Myron Levin, *L.A. Times*, "91 Memo Warned of Mercury in Shots," Feb. 8, 2005 *available at* http://www.ahrp.org/infomail/05/02/08.php; electronic copy of 1991 Dr. Maurice Hilleman memo on file with author.

[280] Dan Olmsted, "Olmsted on Autism: 1979 Wyeth Memo on DPT," Aug. 12, 2008, http://www.ageofautism.com/2008/08/by-dan-olmsted.html, including pdf of the underlying memo, alleged to be Wyeth "internal correspondence."

[281] DAVID KIRBY, EVIDENCE OF HARM, MERCURY IN VACCINES AND THE AUTISM EPIDEMIC: A MEDICAL CONTROVERSY 235-36 (2005).

the Department of Justice's recent *amicus* brief on behalf of industry in *Bruesewitz v. Wyeth*[282] and HHS Secretary's Sebelius' discouragement of press inquiries into vaccine safety.[283] Given this allegiance of government and industry interests, the absence of the ordinary legal protections to informed consent and the right to sue take on heightened significance.

E. Children's Health Problems

American infants and children are experiencing widespread chronic health problems. Fourteen percent have (or have had) asthma;[284] 9% have attention deficit hyperactivity disorder;[285] 8% have a learning disability;[286] 2% have an allergic condition;[287] and 1% has an autism spectrum disorder,[288] with substantially higher rates among boys than girls for many of these conditions. The prevalence of these disorders is unprecedented. High infant mortality in the U.S. is similarly troubling. According to Central Intelligence Agency statistics, the U.S. ranked 28th among world nations for infant mortality, the death rate before one year of age, behind almost all other developed nations.[289]

There are plausible links between vaccines and these troubling health statistics.[290] Petitions in the Court of Federal Claims for vaccine injury show that many individuals think their health problems are vaccine-related.[291] It is scientifically plausible that childhood vaccines may play a role in children's health problems today.

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[282] Brief for the United States As *Amicus Curiae* Supporting Respondents, Bruesewitz v. Wyeth, *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/09-10/09-152_RespondentAmCuUSA.pdf.

[283] *See* Allen interview with HHS Secretary Sebelius, *supra* note 220.

[284] Summary Health Statistics for U.S. Children: National Health Interview Survey, 2009, http://www.cdc.gov/nchs/data/series/sr_10/sr10_247.pdf , asthma data at 25.

[285] *Id.* at 27, ADHD data.

[286] *Id.* at 27, learning disability data.

[287] *Id.* at 26, allergy data.

[288] CDC Data and Statistics, Autism Spectrum Disorders, at http://www.cdc.gov/ncbddd/autism/data.html.

[289] CIA World Factbook at https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html.

[290] See Gallagher & Goodman, *supra* note 17 on developmental disabilities and McDonald *et al*, *supra* note 17 on asthma. The Vaccine Injury Table, *supra* note 165, indicates death as a possible sequela of vaccination.

[291] The VICP has compensated claims for neurological and behavioral disorders. *See, e.g.*, Bricker v. Sec'y of Dep't of Health & Human Servs., 1995 U.S. Claims LEXIS 109 (Fed. Cl. 1995); Fuller v. Sec'y of Dep't of Health & Human Servs., 1996 U.S. Claims LEXIS 17 (Fed. Cl. 1996); Cook v. Sec'y of Dep't of Health & Human Servs., 2005 U.S. Claims LEXIS 297 (Fed. Cl. 2005). Parties have also alleged that vaccines have caused diabetes and autism, but those claims have generally been denied compensation. *See, e.g.*, Dieudonne v. Sec'y of Dep't of Health & Human Servs., 1996 U.S. Claims LEXIS 202 (Fed. Cl. 1996) (denying compensation for diabetes claim); Meyers v. Sec'y of Dep't of Health & Human Servs., 2006 U.S. Claims LEXIS 142 (Fed. Cl. 2006) (denying compensation for diabetes claim); Cedillo v. Sec'y of Dep't of Health & Human Servs., 2010 U.S. App. LEXIS 17900 (Fed. Cir. 2010) (denying compensation for autism claim); Hazlehurst v. Sec'y of Dep't of Health & Human Servs., 604 F.3d 1343 (Fed. Cir. 2010) (denying compensation for autism claim).

IV. Reinterpreting *Jacobson* and Amending the 1986 Law

Restoring the requirements of emergency and imminent harm to justify compulsion, as *Jacobson* prescribed, would end some of THE state police power abuses that exist today. In all non-emergency situations, children and adults should have the right to informed consent and the right to sue manufacturers for vaccine injury.

Today's childhood vaccination mandates against non-fatal, non-contagious and low prevalence diseases do not comport with *Jacobson*. Furthermore, vaccination of children alone cannot create or maintain herd immunity for the entire population, the justification for the mandate in *Jacobson* in the first place. There is a troubling appearance that the vaccines imposed exclusively on children today are not necessary, failing to meet the requirements of *Jacobson*.

States compel vaccination for children that they do not compel for adults, raising the question whether these mandates violate equal protection. While the Supreme Court in *Zucht* upheld a mandate exclusively for children, the smallpox mandate at issue was radically different than today's context. Before *Jacobson*, courts found vaccination mandates to be unconstitutional because of race discrimination.[292] Because of the 1986 Law's broad liability protections and financial incentives for industry and doctors, there are reasons other than public health for ACIP to include vaccines on its recommended list. "History supports the view that coercive laws have largely targeted disadvantaged minorities."[293] Children are at least arguably a disadvantaged minority with no direct political or judicial representation. In the first two years of life when children are recommended to be vaccinated most, they literally cannot speak.[294] Adults would likely be unwilling to tolerate vaccination mandates similar to those the government imposes on children. Indeed, adult healthcare workers in New York State, faced with the prospect of a single compulsory H1N1 vaccine for employment in 2009, mounted a successful political and legal challenge to overturn the mandate.[295]

Several childhood vaccines in state mandates today, such as vaccines against hepatitis B, human papilloma virus (HPV) and tetanus,[296] are not rationally related to school attendance. Hepatitis B is transmissible through intravenous needle exchange or sexual contact; HPV is

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[292] *Wong Wai*, 103 F. at 10.

[293] Mariner *et al*, *supra* note 95, at 588.

[294] Most vaccines are recommended for the first 15 months of life. Recommended Immunization Schedule for Persons Aged 0 Through 6 Years – United States, 2010, http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_0-6yrs-schedule-pr.pdf.

[295] A New York State judge in Albany issued a temporary restraining order suspending the regulation and the New York health authorities then declined to seek further enforcement. *See* Anemona Hartocollis & Sewell Chan, *Albany Judge Blocks Vaccination Rule*, N.Y. TIMES, Oct. 16, 2009, http://www.nytimes.com/ 2009/10/17/ nyregion/17vaccine.html.

[296] For CDC descriptions of diseases and transmission of hepatitis B, *see* http://www.cdc.gov/hepatitis/B/index.htm; for HPV, *see* http://www.cdc.gov/hpv/WhatIsHPV.html; for tetanus, *see* http://www.cdc.gov/vaccines/vpd-vac/tetanus/in-short-both.htm#trans.

transmissible through heterosexual intercourse. These transmitting activities are not part of school curricula. Tetanus is transmitted through deep wound punctures and is not contagious. No child unvaccinated for tetanus poses any risk of contagious disease to another child.

In an imaginable judicial challenge today, a school-aged plaintiff might argue that certain compulsory vaccines, including vaccines for hepatitis B, seasonal influenza, varicella, HPV and tetanus, fail to meet *Jacobson*'s necessity test. These vaccines are not rationally related to school (hepatitis B, HPV),[297] or the disease is not contagious (tetanus),[298] or the illness does not pose fatal risks or imminent harm to the individual or society (varicella and seasonal influenza).[299] Such an approach might substantially reduce a state's vaccination mandates, eliminating certain vaccines that have been added since 1986.

Alternatively, a child might argue that the sheer number of childhood compulsory "unavoidably unsafe" vaccines is oppressive and argue that the 14th Amendment rights to due process and equal protection require that individuals be able to refuse all vaccines except those imposed in situations of emergency and imminent harm. In such a challenge, the absence of any state mandates for any adult population might indicate that childhood mandates are discriminatory and violate equal protection. While *Zucht* upheld a school mandate for children alone, the 1922 context was radically different than the context today. A challenge today might have the effect of either initiating compulsory state mandates for adults or transforming many compulsory vaccinations into recommended ones.

A challenge might argue that outside of the vaccination context, courts have dramatically circumscribed *Jacobson*'s application since 1905. While the Supreme Court used *Jacobson* in 1927 to justify forced sterilization of mentally retarded women as a valid exercise of the police power, the Supreme Court struck down that application in 1978, finding a right to reproductive liberty.[300] Many critics now view that use of the police power to sterilize healthy women against their will as a gross civil rights abuse. Courts have similarly circumscribed government-imposed quarantine and military conscription, the police power to which Justice Harlan analogized the vaccination power in *Jacobson*.[301]

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[297] *Id.*

[298] *Id.*

[299] For CDC description of varicella, *see* http://www.cdc.gov/vaccines/vpd-vac/varicella/in-short-adult.htm#desc and for seasonal flu, *see* http://www.cdc.gov/flu/keyfacts.htm.

[300] Buck v. Bell, 274 U.S. 200 (1927) ("The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough." (citing *Jacobson*, 197 U.S. 11)), *overruled by* Griswold v. Connecticut, 381 U.S. 479 (1965); *See also* Mariner et al., *supra* note 95, at 584 ("With the Court's imprimatur of involuntary sterilization laws, more than 60,000 Americans, mostly poor women, were sterilized by 1978.").

[301] Mariner *et al*, *supra* note 95, at 586 on quarantine ("While it [the Supreme Court] has not decided a case that involved isolation or quarantine for disease, it has held that civil commitment for mental illness is unconstitutional unless a judge determines the person is dangerous by reason of a mental illness. Assuming, as most scholars do, that the law governing commitment to a mental institution also applies to involuntary confinement for contagious diseases, the government would have the burden of proving, by "clear and convincing evidence," that the individual actually has, or has been exposed to, a contagious disease *and* is likely to transmit the disease to others if not

A court would not need to overrule *Jacobson*; it would simply be required to examine evidence of necessity and imminent harm. Few compulsory childhood vaccines today are warding off infectious disease threats that would reach the high threshold *Jacobson* set. And actual uptake of childhood vaccines might or might not change by reducing the number of compulsory ones. Limiting compulsion would simply allow doctors and parents to make individualized choices.

The right of philosophical exemption, or the right to refuse compulsory vaccination, exists today by statute in 22 states. A majority of the U.S. population enjoys this right.[302] Such a right has existed by statute in the United Kingdom since 1898 and exists under constitutional law in Canada, Australia, Scandinavia, Germany and several other developed countries.[303] Some countries, such as Japan, have no compulsory vaccination laws and achieve high rates of vaccine uptake through persuasion alone.[304] There is no evidence that jurisdictions with rights of philosophical or religious exemption have higher burdens of infectious disease or less favorable overall health outcomes.[305]

In addition to courts' restoring *Jacobson*'s plain meaning, Congress should consider revising the 1986 Law's liability protections for manufacturers and doctors. The law has failed to achieve its stated purposes to make vaccines safer and to compensate injured children

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confined."). For conscientious objection, Congress has allowed conscientious objection from military service since 1864 but required the objection to be based on religious belief. However, the Supreme Court has interpreted the statute broadly, allowing that sincere objections "based on 'moral, ethical, or religious beliefs about what is right or wrong'" fall within the definition of religion. Daniel A. Salmon & Andrew W. Siegel, *Religious and Philosophical Exemptions from Vaccination Requirements and Lessons Learned from Conscientious Objectors from Conscription*, 116 PUB. HEALTH REPS. 289, 292 (July – Aug. 2001).

[302] The following states have philosophical exemptions: Arizona, Arkansas, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, Missouri, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Vermont, Washington, and Wisconsin. *See* States With Religious and Philosophical Exemptions from School Immunization Requirements, *supra* note 87.

[303] There is no mandatory vaccination in the United Kingdom. *Childhood Immunisation: A Guide for Healthcare Professionals*, BRIT. MED. ASS'N BD. OF SCI. & EDUC. (June 2003), http://www.bma.org.uk/images/childhoodimm_tcm27-20002.pdf [hereinafter *Childhood Immunisation*]. Scandinavia and Germany also rely on voluntary vaccination rather than compulsion. *Id.* There are some vaccination requirements in Australia, but there is a broad right of conscientious objection. Salmon, *supra* note 100, at 438. Some provinces in Canada require vaccines but allow conscientious objection, and the country as a whole does not mandate vaccination. Vaccine Safety FAQ, Pub. Health Agency of Can. (April 14, 2008), http://www.phac-aspc.gc.ca/im/vs-sv/vs-faq16-eng.php.

[304] *Id., Childhood Immunisation* at 5.

[305] For example, in 2008, the United Kingdom with a population of roughly 61 million, had five reported cases of diphtheria, 1,445 reported cases of measles, and 2,625 reported cases of mumps. Immunization Profile – United Kingdom of Great Britain and Ireland, World Health Organization, http://apps.who.int/immunization_monitoring/en/globalsummary/countryprofileresult.cfm?C='gbr'. Similarly, in 2008 Australia had a population of roughly 21 million and had zero reported cases of diphtheria, 65 reported cases of measles, and 286 reported cases of mumps. Immunization Profile – Australia, World Health Organization, http://apps.who.int/immunization_monitoring/en/globalsummary/countryprofileresult.cfm?C='aus'. In the United States, where choice is more limited, in 2008 with a population of roughly 311 million, there were zero reported cases of diphtheria, 43 reported cases of measles, and 800 reported cases of mumps. Immunization Profile – United States of America (Aug. 3, 2010).

generously and swiftly.[306] By making the VICP optional, Congress might make the tax-financed compensation system work. If families had the choice to file claims in civil courts or in the VICP, industry and doctors would have strong financial incentives to make the VICP as petitioner-friendly as possible, providing quick, generous, administrative compensation. Industry and doctors then would have incentives to put all recognized vaccine-related injuries on the Vaccine Injury Table to induce families to take their claims there rather than the tort system. Manufacturers would still be able to substantially limit their liability by making the VICP a better alternative than tort litigation in civil court, as Congress intended.

Congress should also consider repealing the 1986 Law's provisions which abrogate the right to proper warnings. It is troubling that the nation's most vulnerable population is deprived of accurate and complete information, unlike any other civilian group. Reinstating manufacturer and medical liability and the requirement of proper warnings would restore the safety incentives that the 1986 Law improvidently removed.

CONCLUSION

In true emergencies of epidemic disease that threaten an entire population, such as smallpox or anthrax, states have the right and responsibility to adopt measures to address them. *Jacobson* and *Zucht* upheld vaccination mandates for adults and children in this context. In non-emergency situations, however, as predominantly exist today, compulsory vaccination mandates exclusively for children are unreasonable and oppressive and have led to the perverse results of which *Jacobson* warned. Giving effect to *Jacobson*'s plain meaning and amending the 1986 Law would restore the ordinary tort law protections of informed consent and the right to sue. Such a move away from compulsion would restore children's rights and better protect their health and safety.

[306] *See* Brief of Vaccine Injured Petitioners Bar Association, *supra* note 160, at 7.

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STATE OF VERMONT
SENATE COMMITTEE

Senate Committee on Health and Welfare

AGENDA

Room 17

January 24, 2012 - January 27, 2012

Tuesday, January 24, 2012

9:00 AM **Senate Floor**

\- **Chairs Meeting**

\- **S. 199 - An act relating to immunization exemptions and the immunization pilot program**

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

Curtis Gross, DC, Middlebury Chiropractic

Harry Chen MD, Commissioner, Department of Health

Dr. Louis DiNicola, President, Vermont Chapter of the American Academy of Pediatrics

Christine Finley, Immunization Program Chief, Department of Health

Hannah Foote, Student, University of Vermont College of Medicine

Bud Vana, Student, University of Vermont College of Medicine

Roger Clapp, Executive Director, March of Dimes

Breena Holmes MD, Director of Maternal and Child Health

Paul Harrington, Executive Vice-President, Vermont Medical Society

Wednesday, January 25, 2012

9:00 AM **Prescription Drug Diversion**

Joint with House Human Services and Senate Judiciary

Chadd Lackey, Counsel, New Jersey State Commission of Investigation

11:00 AM **Substance Abuse Treatment**

Mental Health and Substance Abuse:Co-Occurring Disorders

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

11:30 AM **S. 242 - An act relating to prescribing a controlled substance**

Rachel Allen, Law Clerk, Legislative Council

Thursday, January 26, 2012

9:00 AM **Blueprint for Health**

Annual Report, Joint with House Health Care- Room 10

Craig Jones, Director, Vermont Blueprint for Health

11:15 AM **Catamount Health**

Merger of Catamount Health and the State Health Care Resources Fund

Mark Larson, Commissioner, Department of Vermont Health Access

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

Friday, January 27, 2012

9:00 AM **Long Term Care**

Blueprint Integration

Craig Jones, Director, Vermont Blueprint for Health

Nancy Eldridge, Executive Director, LeadingAge Vermont

Peter Cobb, Director, Vermont Assembly of Home Health and Hospice Agencies

Susan Wehry, Commissioner, Department of Disabilities, Aging & Independent Living

Marybeth McCaffrey, Director, Division of Disability and Aging Services

10:45 AM **Long Term Care Partnership**

Fiscal Analysis

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

Marybeth McCaffrey, Director, Division of Disability and Aging Services

11:00 AM **S. 197 - An act relating to hospital-based outpatient fees**

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

David Martini, General Counsel, Department of Banking, Insurance, Securities & Health Care Administration

Bea Grause, President, Vermont Association of Hospitals and Health Systems

Michael Del Trecco, Vice President of Finance, Vermont Association of Hospitals and Health Systems

Steven Josselyn, Resident, Rutland- via phone

12:00 PM **S. 191 - An act relating to rational treatment of chronic pain**

Steven Mann, Ph.D, Occupational Disability Management Center

Jennifer Carbee, Legislative Counsel, Office of Legislative Council

Gini Milkey, Director, Coalition of Vermont Elders (COVE)

S.199

Introduced by Senator Mullin

Referred to Committee on

Date:

Subject: Health; public health; communicable disease; immunization

Statement of purpose: This bill proposes to extend the termination date of the immunization pilot program and remove the exemption from immunization on philosophical grounds.

An act relating to immunization exemptions and the immunization pilot program

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 1122(a) is amended to read:

(a) A person may remain in school or in the child care facility without a required immunization:

* * *

(3) If the person, or in the case of a minor, the person's parent or guardian, states in writing that the person, parent, or guardian has religious beliefs ~~or philosophical convictions~~ opposed to immunization.

Sec. 2. 18 V.S.A. § 1130(b)(1) is amended to read:

(b)(1) The department of health shall establish an immunization pilot program with the ultimate goal of ensuring universal access to vaccines for all Vermonters at no charge to the individual and to reduce the cost at which the state may purchase vaccines. The pilot program shall be in effect from January 1, 2010, through December 31, ~~2012~~ 2014. During the term of the pilot program, the department shall purchase, provide for the distribution of, and monitor the use of vaccines as provided for in this subsection and subsection (c) of this section. The cost of the vaccines and an administrative surcharge shall be reimbursed by health insurers as provided for in subsections (e) and (f) of this section.

Sec. 3. EFFECTIVE DATE

This act shall take effect on passage.

More parents are rejecting vaccinations for their children

- They consider the vaccines more dangerous than the disease
- They prefer natural rather than artificial immunity
- They have a vaccine-injured child (a growing number)
- They have religious or philosophical objections to vaccination

The numbers are large...

- *USA Today.* Oct. 30, 2000: "Roughly one fourth of American parents have serious concerns over the safety of vaccinations their children receive."
- *Wall Street Journal.* Aug 1, 2003, p. 1. "There is growing opposition to the number of shots required."

Robert Mendelsohn, MD

- "There is no convincing scientific evidence that mass inoculations can be credited with eliminating any childhood disease…I urge you to reject all inoculations for your child." Mendelsohn R. *How to raise a healthy child…in spite of your doctor*. Chicago: Contemporary Books. 1984:210.

Medical groups oppose vaccine mandates

- The Association of American Physicians and Surgeons calls for an end to mandatory childhood vaccines. "Our children face the possibility of death or serious long-term adverse effects from mandated vaccines that aren't necessary or that have very limited benefits." Jane M. Orient, MD, AAPS Executive Director. Nov. 2, 2000. www.aapsonline.org

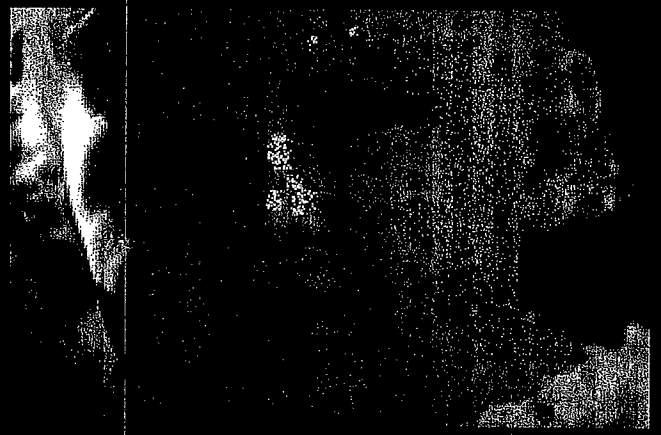
British Medical Association rejects compulsory vaccination

- "We do not believe that compulsory immunization is in any way appropriate ….At the end of the day, it is up to parents to balance the risks and benefits of vaccination." Dr Vivienne Nathanson, head of BMA ethics and science. BBC News, 6/30/03. http://news.bbc.co.uk/1/hi/health/3023538.stm

Example of vaccine "science"

- 2,588 Navajo infants were given Hib, DPT and OPV (the "vaccine" group).
- 2,602 Navajo infants were given DPT, OPV AND lactose (the "placebo" group). Santosham M, Wolff M, Reid R, et al. The efficacy in Navajo infants of a conjugate vaccine consisting of *Haemophilus influenza* type b polysaccharide and *Neissereia meningitidis* outer-membrane protein complex. *New England J of Med*; 1991, 324(25):1767-1772. **Note:** study was ended early because of the large number of deaths and injuries in both groups. Death and injury from a placebo?

- To repeat: we do not know if *any* vaccine is safe because vaccinated children are not compared to non-vaccinated ones in safety tests.
- Also test children are healthy, unlike those often vaccinated in real life.



Is Infant Immunization a Risk Factor for Childhood Asthma or Allergy?

Trudi Kemp,[1] Neil Pearce,[1] Penny Fitzharris,[1] Julian Crane,[1] David Fergusson,[2] Ian St. George,[3] Kristin Wickens,[1] and Richard Beasley[1]

The Christchurch Health and Development Study comprises 1,265 children born in 1977. The 23 children who received no diphtheria/pertussis/tetanus (DPT) and polio immunizations

tions, and 30.0% consultations for other allergic illness. Similar differences were observed at ages 5 and 16 years. These findings do not appear to be due to differential use of health

Immunized children: 23.1% had asthma, 30% had other allergic illnesses.

Non-immunized children: 0% had asthma or other allergic illness.

Robert Mendelsohn, MD

- "Immunization against relatively harmless childhood diseases may be responsible for the dramatic increase in autoimmune diseases…such as cancer, leukemia, rheumatoid arthritis, multiple sclerosis, Lou Gehrig's disease, lupus and Guillain-Barre syndrome."

Doctors rarely report damage

- "Doctors underreport adverse vaccine reactions by 90%." US Food and Drug Administration
  "Investigative Report on the Vaccine Adverse Event Reporting System." NVIC.

James Froeschle, Connaught Laboratories, Swiftwater, Pennsylvania Dr. Froeschle gave information about adverse events following diphtheria and tetanus toxoids (DT) that had been reported to Connaught. From a comparison of spontaneous reports with postmarketing surveillance data, the company estimates about a 50-fold underreporting of adverse events in the passive reporting system. The distribution of types of events, however, was found to be approximately the same; in both cases, the majority of reported events were local reactions or fever. The company has seen a marked decrease in adverse event reports since the inception of VAERS late in

"The company estimates about a 50-fold underreporting of adverse events in the passive reporting system." Froeschle, J. Connaught Laboratories. Adverse events associated with childhood vaccines, evidence bearing on causality. Washington DC: Institute of Medicine presentations. 5/11/92; 328 Appendix. B. http://www.nap.edu/books/0309048958/html/R1.html

One in 500 injuries reported...

- An analysis of the CDC's own data demonstrates that the number of actual injuries from the rotavirus vaccine is 500 times the injuries reported to VAERS.
- http://search.cdc.gov/search97cgi/s97is.dll?queryText=Kaiser+Permanente+and+rotashield&SortField=score&Action=FilterSearch&Collection=CDCALL1&ResultTemplate=nsearchresult.hts&filter=newsearch.hts
- http://www.cdc.gov/nip/ACIP/minutes/acip-min-oct01.rtf

What are the real numbers?

- By Dec 2002, VAERS received 244,424 reports of possible reactions to vaccines including:
  - 99,145 emergency room visits
  - 5,149 life-threatening reactions
  - 27,925 hospitalizations
  - 5,775 disabilities and
  - 5,309 deaths

Question: are vaccinations "effective?"

- What does effective mean?
- CDC: "Effective" means antibodies are produced, not clinical effectiveness (i.e. no disease).
- However, there is often no correlation between antibodies and resistance to disease.

Whooping Cough Caused by *Bordetella pertussis* and *Bordetella parapertussis* in an Immunized Population

"[Pertussis] infections are common in an immunized population...more prevalent than previously documented." 98% were vaccinated in this population.

He Q, Vijanen MK, Arvilommi H et al. Whooping cough caused by Bordetella pertussi and Bordetella parapertussis in an immunized population. *Journal of the American Medical Association*. 1998;280:635-637.

- Outbreaks have occurred in 100% vaccinated populations.

  Morbidity and Mortality Weekly Report. US Govt. 12/29/89/38(S-9):1-18.

- "80% cases of measles are contracted in vaccinated people." *Morbidity and Mortality Weekly Report*. US Govt. 6/6/86/35(22):366-70.

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A PERSISTENT OUTBREAK OF MEASLES DESPITE APPROPRIATE PREVENTION AND CONTROL MEASURES

An outbreak of 137 cases of measles… 98.7% of students were appropriately vaccinated. Davis RM, Whitman ED, Orenstein WA, A persistent outbreak of measles despite appropriate prevention and control measures. *Am J Epidemiol. 1987;126(3):438-449.*

cases, 82 (59.9%) were in school-aged children (aged 5–19 years). Of the 114

Vaccines interfere with transplacental immunity

Girls who are vaccinated have less protection to pass on to their unborn child. (a) More measles now occurs in children less than 1 and adults 25+ (b)

(a) Papania M, Baughman AL, Lee S, et al Increased susceptibility to measles in infants in the United States. Pediatrics. 1999;104(5):e59 National Immunization Program, Epidemiology Program Office, Centers for Disease Control and Prevention, Atlanta, Georgia 30333, USA. (b) MMWR 1991;40:369-372 in *JAMA*;1991;265(24).

Is the rubella vaccine effective?

- Rubella (German measles) is so mild is it often mistaken for a cold. If contracted during 1st trimester pregnancy it *may* cause birth defects (Congenital rubella syndrome – CRS).

Hib Vaccine

- Causes type 1 diabetes
- Reports of death from Hib infection after Hib vaccination
- "The potential risk of the vaccine exceeds the potential benefit." *British Medical Journal* October 23, 1999.

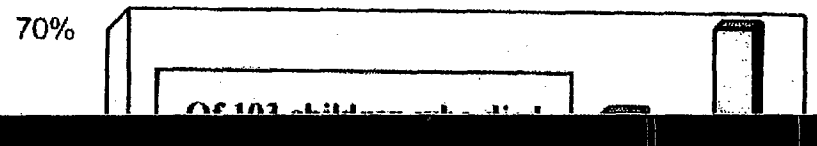
Chickenpox (varicella)

- A mild self-limiting disease that gives permanent life long immunity if caught as a child but is much more dangerous in adults.
- The chances of a child becoming seriously ill and dying from chicken pox are about equal to winning the lottery.

Question: Are vaccine doses personalized?

- A 5 pound premature baby will get the same dosage as a 60 pound 6-year-old. There is no personalization for weight, health or any other reason.
- A single vaccine given to a 6 pound newborn is the equivalent of giving an adult 30 vaccinations on the same day.

The Pertussis Vaccine and Sudden Infant Death Syndrome



"DPT vaccination may be a generally unrecognized major cause of sudden infant and early childhood death…the risks of immunization may outweigh its potential benefits." Torch, WC, Diphtheria-pertussis-tetanus (DPT) immunization: a potential cause of the sudden infant death syndrome (SIDS) American Academy of Neurology, 34th annual meeting, Apr 25-May 1, 1982, *Neurology* 32(4), PT.2

American Academy of Neurology, 34th Annual Meeting: *Neurology* 32(4).

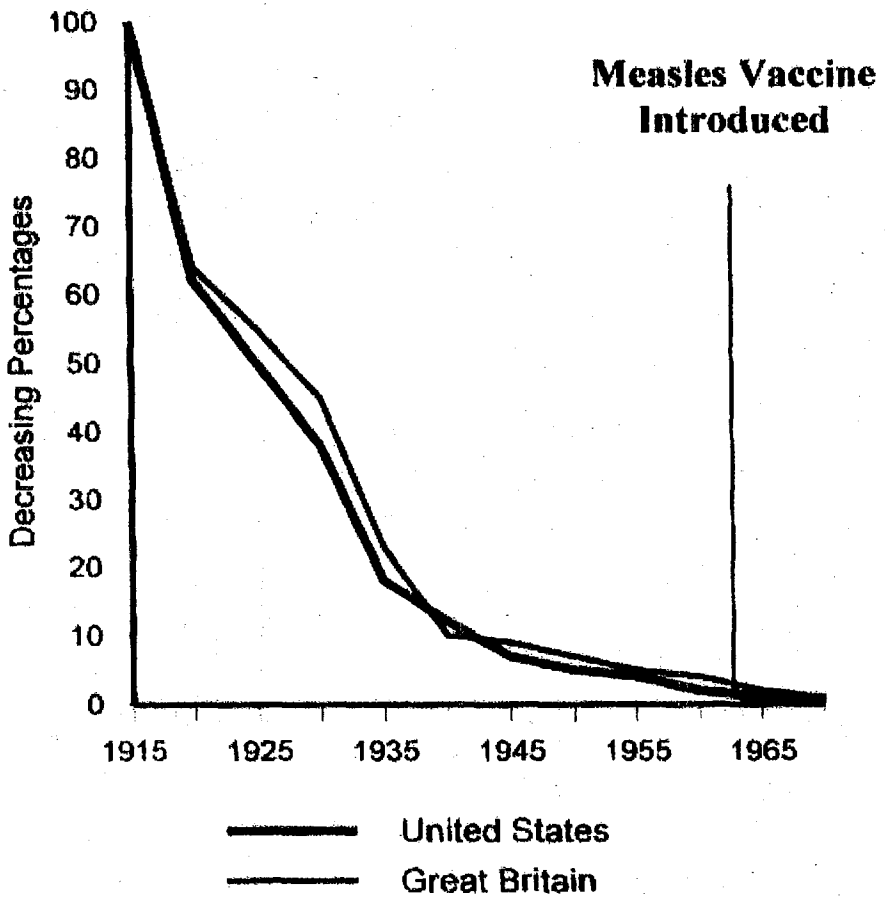
Crib death in Japan

- In 1975 Japan raised the minimum age of vaccination from 2 months to 2 years. Crib death, infantile seizures, meningitis and other infectious diseases in infants virtually disappeared. Japan went from 17th in infant mortality to 1st.
- However serious infectious diseases such as meningitis sharply increased in 2 year olds.

Question: Did vaccines eliminate diseases?

- "Nearly 90% of the total decline in mortality (scarlet fever, diphtheria, whooping cough, and measles) between 1860 and 1965 occurred before the introduction of antibiotics and widespread immunization." Illich, I. *Medical Nemesis*. Chapter 1-The Epidemics of Modern Medicine, NY: Bantam Books 1976

The Measles Death Rate was Decreasing on its Own *Before* the Vaccine was Introduced

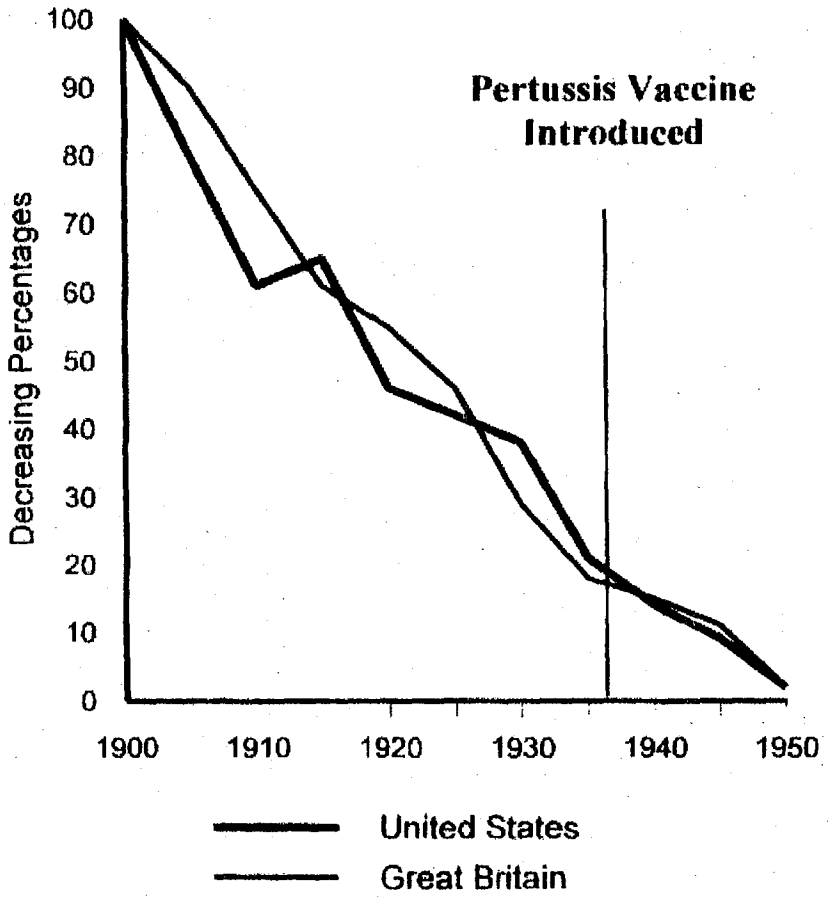


From 1915 to 1958, before the measles vaccine was introduced, the measles death rate in the United States and Great Britain had already declined on its own by 98 percent. Source: *International Mortality Statistics,* 1981.

Measles in vaccinated populations

An Illinois high school with a 99.7% vaccination rate reported 69 cases of measles over a 3-week period. Chen RT, Goldbaum GM, Wassilak SG et al. An explosive point-source measles outbreak in a highly vaccinated population. Modes of transmission and risk factors for disease. *Am J Epidemiol*. 1989;129(1):173-182.

The Pertussis Death Rate was Decreasing on its Own *Before* the Vaccine was Introduced



From 1900 to 1935, *before* the pertussis vaccine was introduced, the death rate from pertussis in the United States and England had already declined on its own by 79 percent and 82 percent, respectively. Source: *International Mortality Statistics* (1981) by Michael Alderson.

THE 1993 EPIDEMIC OF PERTUSSIS IN CINCINNATI

Resurgence of Disease in a Highly Immunized Population of Children

74% of the children had received four or five doses of DPT vaccine and 82% had at least three doses. "It is clear that the whole cell pertussis vaccine failed to give full protection against the disease."

Christie C, Marx M, Marchant, CD, Reising S. The 1993 epidemic of pertussis in Cincinnati. Resurgence of disease in a highly immunized population of children. *New England Journal of Medicine*. 1994;331:16-21.

Dr. Judith Daniels: "We don't know why this is happening. The CDC also doesn't know and this is worrisome." Cincinnati Inquirer

fluorescent-antibody testing only, and 19 percent were diagnosed clinically. The outbreak began in the suburbs during the summer and spread through Greater Cincinnati. Of 255 total cases diagnosed in July through September (195 excess cases over the maximal base-line level of 20 per month in the previous 14 years), 75 percent were in white patients and 67 percent of the patients had private insurance or paid for care out of pocket. In 1993, as compared with 1979 through 1992, there was a shift in incidence to older children. Of the 255 children (31 percent) given diagnoses during the three epidemic months were hospitalized. There were no deaths.

Conclusions. Since the 1993 pertussis epidemic in Cincinnati occurred primarily among children who had been appropriately immunized, it is clear that the whole-cell pertussis vaccine failed to give full protection against the disease. (N Engl J Med 1994;331:16-21.)

Question: What's in a vaccine?

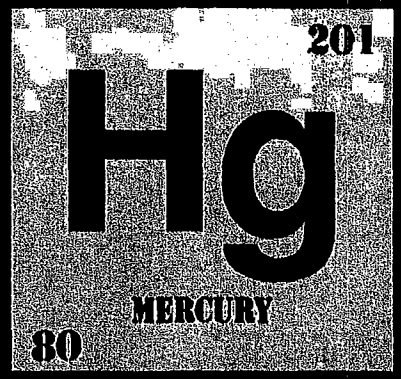
In addition to live and killed bacteria, viri and their toxins, children are injected with some of the most lethal poisons known: formaldehyde, mercury, aluminum, phenol (carbolic acid), borax (ant killer), ethylene glycol (antifreeze), dye, acetone (nail polish remover), latex, MSG, glycerol, polysorbate 80/20, sorbitol…

- ...monkey, cow, chick, pig, sheep and dog tissues and cells (may be contaminated with animal viruses), gelatin, casein, human fetus cells, human viruses, antibiotics, genetically modified yeast, animal, bacterial and viral DNA (may affect recipient's DNA).

Formalin/Aluminum

- Formalin is a dilute formaldehyde solution. Nearly 50 studies have shown a link between formaldehyde exposure and leukemia and brain, colon and lymphatic cancer.
- Aluminum is a neurotoxin that crosses the brain/blood barrier. Neustaedter R. *The Vaccine Guide,* Berkley, CA: North Atlantic Books. 1996.

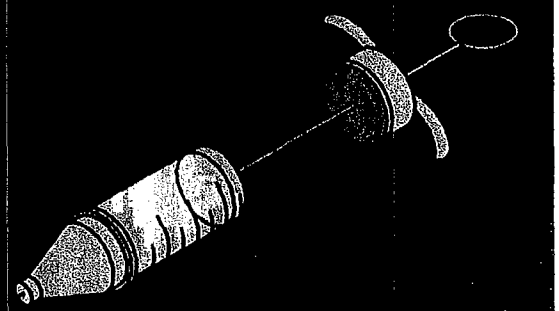
Mercury



- One of the most poisonous substances known to exist in nature.
- Children have received up to 125 times the safe limit of mercury set by the EPA (autism skyrocketed).
- Symptoms of mercury toxicity resemble those of autism.
- Mercury is still in use (as of 2003.)

Natural disease vs. injected disease

- Diseases contracted naturally are ordinarily filtered through a series of immune system defenses (i.e. skin and mucous membranes).
- But when the vaccine virus and chemicals are injected directly into the child's blood stream they have access to all of the major tissues and organs of the body without the body's normal advantage of a total immune response.



Question: Does research support vaccination efficacy/safety?

- "My data proves that the studies used to support immunization are so flawed that it is impossible to say if immunization provides a net benefit to anyone or to society in general. This question can only be determined by proper studies which have never been performed." John B. Classen, M.D., M.B.A.

J. Anthony Morris, Ph.D.

- "There is a great deal of evidence to prove that immunization of children does more harm than good." J. Anthony Morris, Ph.D. former Chief Vaccine Control Officer, US Food and Drug Administration.

Most MMR studies are meaningless, investigation claims

- Most MMR studies are meaningless, investigator claims

"There is some good research, but it is overwhelmed by the bad. The public has been let down because proper studies have not been done."

Thomas Jefferson, M.D. *The Telegraph* 10/27/2002

http://www.guardian.co.uk/medicine/story/0,11381,805576,00.html

Smallpox

- "It is pathetic and ludicrous to say we ever vanquished smallpox with vaccines, when only 10% of the population was ever vaccinated." Glen Dettman, MD

Harris Coulter, Ph.D.

- "When I once pointed out to an officer of the United States Public Health Service that articles on vaccination 'adverse reactions' often misrepresented the facts and were rarely supported by statistical or other evidence, he responded: 'That's true, but it doesn't make any difference; we already know that these vaccines are entirely safe.'" Harris L. Coulter, Ph.D. A word about official US pro vaccination literature. In *The Coulter Reader*. Philadelphia, PA: Koren Publications. 2003.

Do vaccines cause meningitis?

- Meningitis increased in 1990 after the MMR-vaccine was introduced in New Zealand. A meningitis outbreak in Brazil was linked to MMR vaccination 3 weeks after "National vaccination Day." *American Journal of Epidemiology*. 2000;151:524-530.

ROGER CLAPP 1/24/12 19
/IMMUNIZATION

March of DimesFoundation

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Waterbury, VT 05676
Telephone (802) 560-4822
Fax (802) 560-4824
www.marchofdimes.com/Vermont

January 24, 2012

Senator Claire Ayer
Members of the Senate Health and Welfare Committee
Vermont State House
Montpelier, VT 05633-5301

Dear Senator Ayer and Senate Health and Welfare Committee Members:

Together with the organizations listed below, we are writing to urge you to consider S.199 in your committee this session.

The work of the March of Dimes Foundation improves the health of women, infants and children. S.199 speaks directly to our mission and the missions of the organizations who have signed on to this letter..

Over the past several years, immunization rates in Vermont have declined. This is because Vermont is one of the most lenient states in the country in allowing philosophical exemptions to the immunization requirement. Although we had one of the highest immunization rates in the country just 10 years ago, we have fallen to one of the lowest rates now.

Low immunization rates put everyone at risk for contracting serious communicable diseases – diseases which are preventable with immunizations.

According to the Department of Health, vaccination rates for incoming kindergartners have dropped from 93% in 2006 to 83% today. In addition, there were 90 reported cases of whooping cough in Vermont this past year – compared to only 18 cases in 2010 (a leading indictor of declining immunization rates.)

We urge you not to wait for adverse health effects before addressing this issue. Please take up, and pass, S.199.

Sincerely,

Roger Clapp, State Director, Vermont Chapter of the March of Dimes

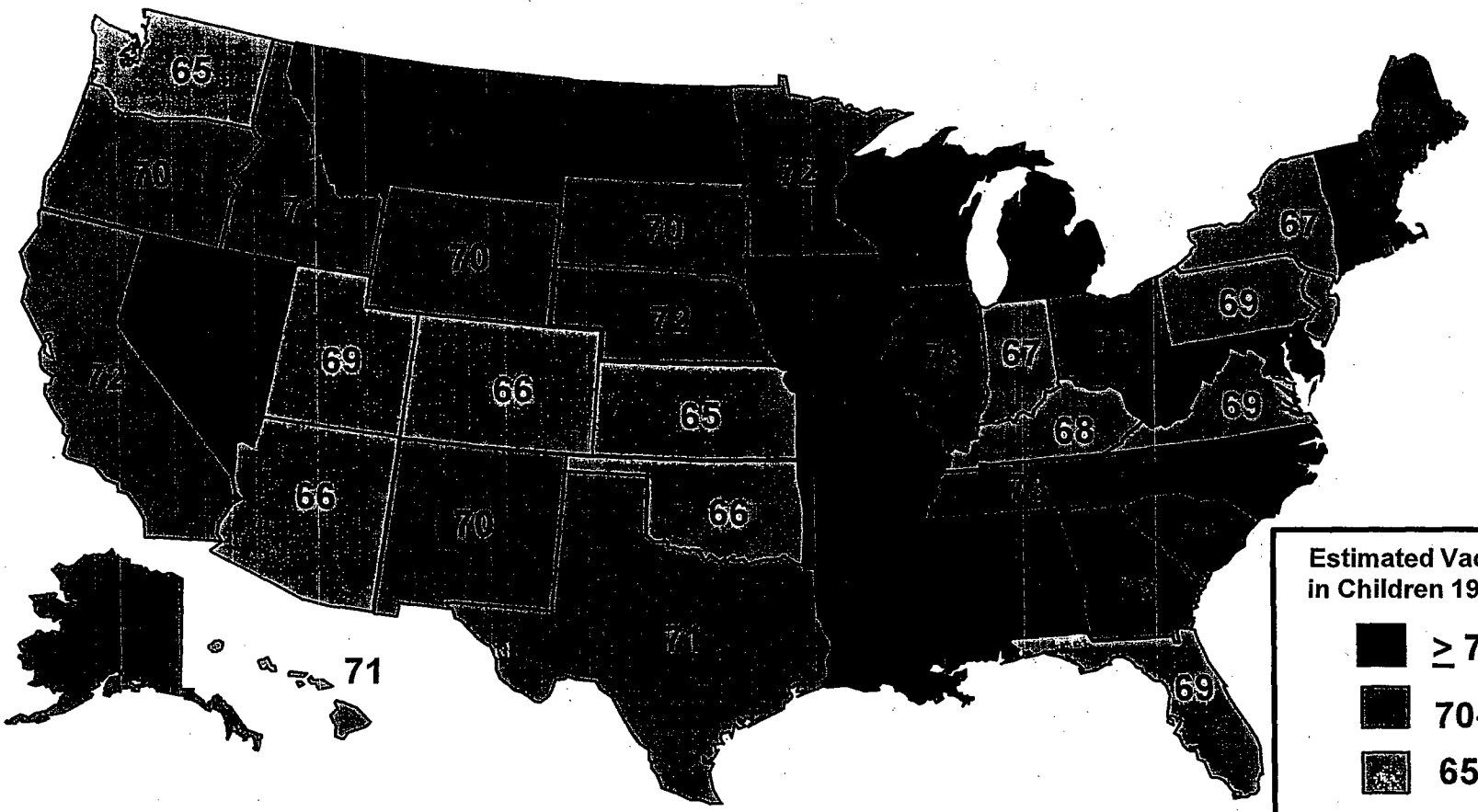
Amer. Academy of Pediatrics, VT Chapter
Boys & Girls Clubs of Burlington
Twin States Network
Vermont Nurse Practitioners Association
Vermont Medical Society
Voices for Vermont's Children
Vermont Campaign for Health Care Security

CHRISTINE FINLEY 1/24/12
IMMUNIZATIONS

Millions of U.S. Children Are at Risk for Serious Disease

Nationwide, 71% Children 19-35 Months Old Are Adequately Vaccinated*

The Healthy People 2020 goal is 80%



VT	60
NH	73
MA	76
RI	70
CT	76
NJ	67
DE	79
MD	78

Estimated Vaccine Coverage in Children 19-35 Months Old

- ≥ 75%
- 70-74%
- 65-69%
- ≤ 64%

*Routine childhood vaccines: 4+DTP, 3+Polio, 1+Measles-containing vaccine, 3+HepB, 1+Varicella, 4 PCV. Hib is excluded for 2009 due to vaccine shortages.

Source: *CDC National Immunization Survey 2009*

March 2011

Association of State and Territorial Health Officials
www.ASTHO.org

astho™

Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases

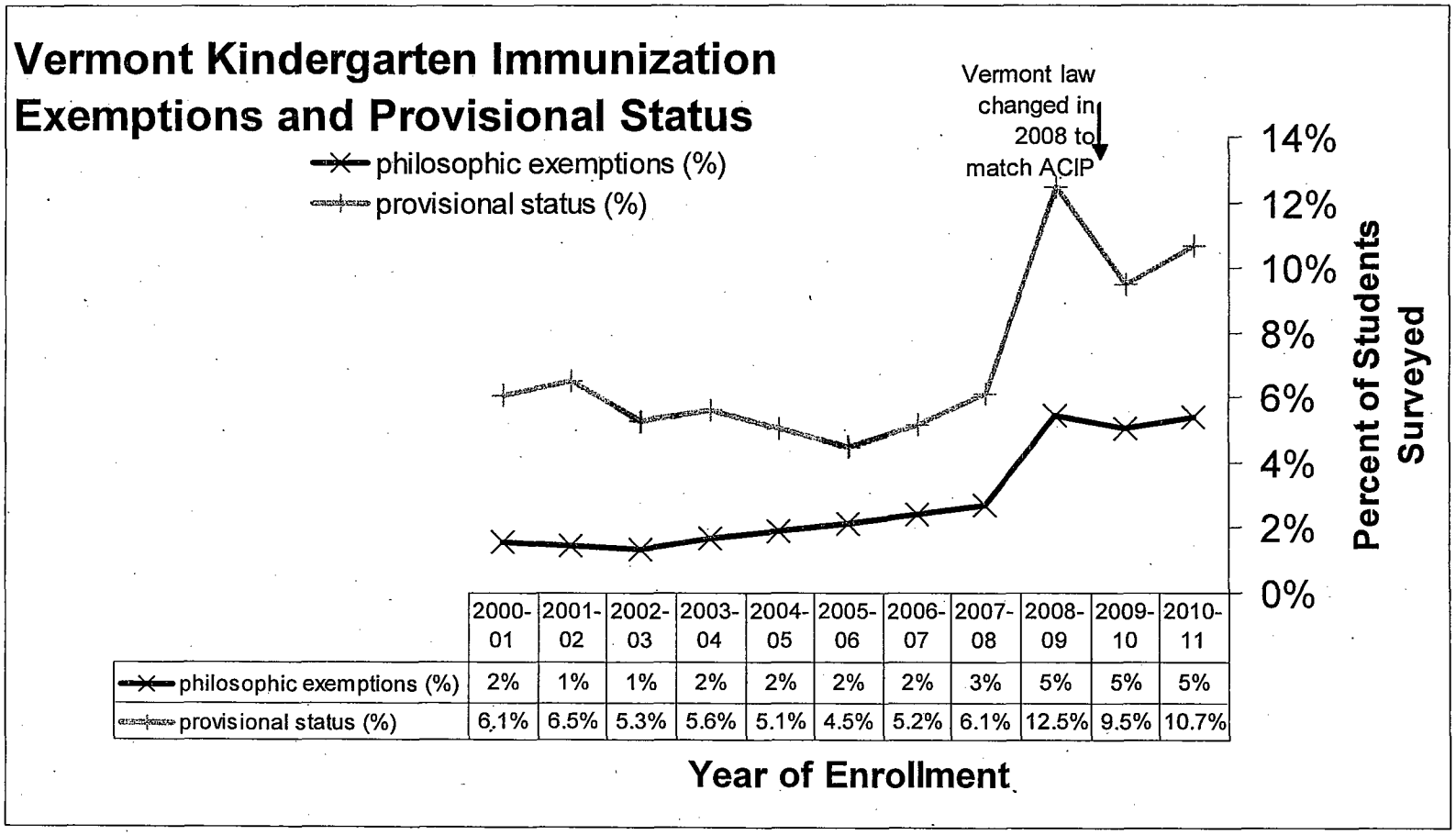
Disease	20th Century Annual Morbidity†	2011 Reported Cases ††	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Measles	530,217	212	> 99%
Mumps	162,344	370	> 99%
Pertussis	200,752	15,216	92%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	4	> 99%
Congenital Rubella Syndrome	152	0	100%
Tetanus	580	9	98%
Haemophilus influenzae	20,000	8*	> 99%

†Source: JAMA. 2007;298(18):2155-2163

††Source: CDC. MMWR January 6, 2012;60(51);1762-1775. (provisional 2011 data)

* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 14 cases of Hib are estimated to have occurred among the 237 reports of Hi (< 5 years of age) with unknown serotype.

Vermont Kindergarten Immunization Exemptions and Provisional Status



	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11
philosophic exemptions (%)	2%	1%	1%	2%	2%	2%	2%	3%	5%	5%	5%
provisional status (%)	6.1%	6.5%	5.3%	5.6%	5.1%	4.5%	5.2%	6.1%	12.5%	9.5%	10.7%

HANNAH FOOTE + BUD VANA 19
IMMUNIZATIONS 1/24/12

The UNIVERSITY of VERMONT
COLLEGE OF MEDICINE

Hannah Foote MS II and Bud Vana MS II
Presentation to the Vermont Senate
Committee on Health and Welfare
January 24, 2012

Vaccine Related Resources

Websites

- www.cdc.gov/acip
- www.immunize.org
- www.vaccine.chop.edu
- www.ecbt.org
- www.immunizationinfo.org
- www.vaccinesafety.edu
- www.pkids.org

Books

- Vaccines and Your Child: Separating Fact and Fiction - Paul Offit
- The Panic Virus - Seth Mnookin

Interviews

- Dr. Paul Offit interviewed by Stephen Colbert http://www.colbertnation.com/the-colbert-report-videos/372812/january-31-2011/paul-offit
- Michael Specter, author of Denialism, interviewed by Jon Stewart http://www.thedailyshow.com/watch/thu-december-3-2009/michael-specter

Vaccines and your child

Bud Vana and Hannah Foote
UVM COM MSII

How does your body naturally respond to an infection?

- We call the body's response to bacteria and viruses the **immune response.**
- The body has a lot of tools to use, but the most important one is called an **antibody.**
- When a virus or bacteria infects your body, it makes antibodies that are specially designed to kill that particular virus or bacteria. The body will then keep these antibodies forever.

2

What is a vaccine?

- Vaccines are substances that cause the body to respond in a *similar* way that it would to an infection. HOWEVER,
- Vaccines do not cause the same size response as diseases do, BUT
- Vaccines do not cause the sickness and death that diseases can cause.

3

How do we know vaccines work?

- It's very hard, because when they work, we don't see anything!
- It's also very hard because you can never really PROVE that something isn't there. (How can you prove that your lost car keys are not somewhere in your house?!)
- BUT we can see a reduction in diseases over time when vaccines are given. More on this later.

4

When do we give vaccines?

- As soon as we can. But we have to wait until:
  - The child no longer has the antibodies that came from his or her mother, and until
  - The child's immune system is working well enough to produce antibodies
- THERE IS NO HARM IN VACCINATING TOO EARLY! The vaccine just might not work
- Even though the immune system of infants is still developing, they are able to respond to thousands of different particles a day. (Think about how many they are exposed to after crawling across the kitchen floor!)

5

What are the risks of vaccines?

All medical treatments have some risks

- Allergies: people with allergies to certain ingredients in vaccines (such as egg) may experience an allergic response to those allergens.
- Non-allergic reactions: very rarely (1/25000) people may experience a more serious reaction such as a period of easy bleeding.

6

How are vaccines made and tested for safety?

- After testing the substances outside of a body, they are tested in animals for toxicity.
- The substance is then tested in humans to determine the appropriate dose.
- The full vaccine is then prepared by adding the other ingredients necessary for storage, transport, and administration.
- Finally, thousands and thousands of volunteers are given the vaccine to test its safety and effectiveness.
- The way that different vaccines interact with each other is also studied.

7

How do we know if problems are caused by vaccines?

- Experiments that directly compare groups of people who have received the vaccine to those who have not are the best way to answer this question.
- For example, the autism rate in children who received the MMR rate was the same as the autism rate in children who did not.

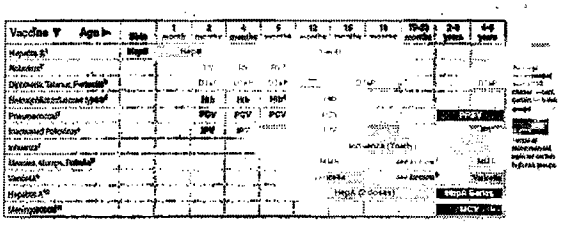
8

What happens if there is a reaction caused by a vaccine?

- Vaccine Adverse Events Reporting System (VAERS): vaers.hhs.gov/index.
- If vaccines are suspected to cause a reaction, a study would be done to assess the reaction.
- For example: the first rotavirus was shown to cause a higher rate of problems in the children's intestines who had received the vaccine. This process allowed the vaccine to be improved.

9

The recommended schedule



This schedule was developed by the Center for Disease Control

10

A myth about vaccines

- "Too many vaccines weaken the immune system"
  - PEOPLE GET FEWER PRIMARY AND SECONDARY INFECTIONS WHEN THEY ARE VACCINATED.
  - People who are vaccinated are still exposed to many, many, many germs that allow the immune system to develop normally.
  - Asthma and allergies do not increase in people who have been vaccinated.

11

Some specific vaccine preventable illnesses

- Hepatitis B
- Rotavirus
- Diptheria
- Tetanus
- Pertussis
- Haemophilus influenza B
- Polio
- Measles
- Mumps
- Rubella
- Varicella

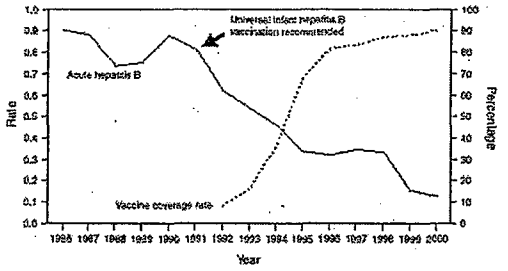
12

Hepatitis B

- Acute infection of the liver that can become chronic or lead to death.
- Rates in the US vary, but can be higher in areas with high rates of immigrants. 5% of the world is chronically infected.
- Vaccine is a series of three shots given at birth, 1 month, and 6 months.

13

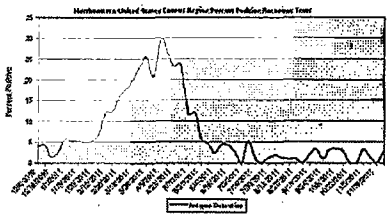
Hepatitis B



14

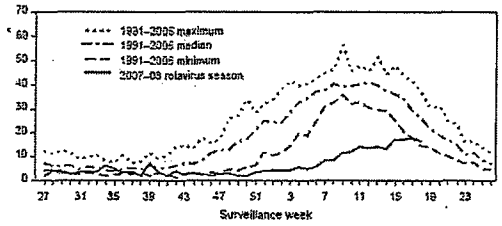
Rotavirus

- A major cause of severe, sometimes lethal diarrhea that previously caused a half a million death per year in children under 5.



15

Rotavirus



16

Rotavirus

Vaccine is 3 oral doses given at 2, 4, and 6 months

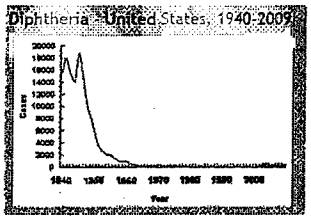
17

Diphtheria

- Diphtheria causes a thick covering in the back of the throat that can lead to breathing problems, paralysis, heart failure, and even death.
- Vaccine is given in combination with tetanus and pertussus at 2, 4, 6, and 15 months.

18

Diphtheria



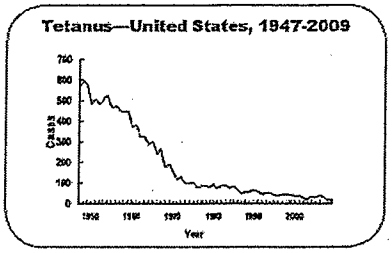
19

Tetanus

- A serious disease that causes painful tightening of the muscles all over the body that can lead to death in about 1 in 10 cases
- Vaccine is given in combination with diphtheria and pertussis at 2, 4, 6, and 15 months

20

Tetanus



21

Pertussis

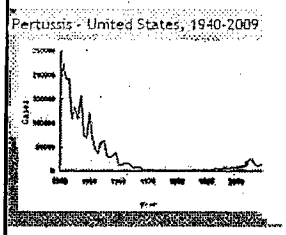
- Also called whooping cough, this disease was one of the most common childhood diseases and a major cause of childhood death in the United States before the vaccine became available.
- It begins like an upper respiratory illness but can quickly become more serious.
- Vaccine is given in combination with diphtheria and tetanus at 2, 4, 6, and 15 months.

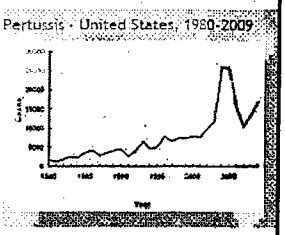
22

Pertussis

23

Pertussis





Notice the increasing rates in the last 20 years.

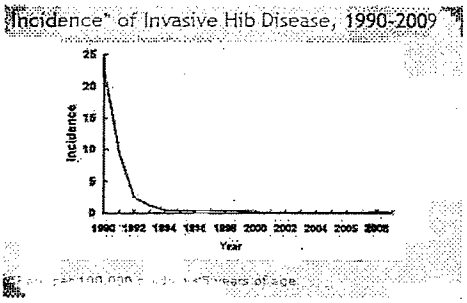
24

Haemophilus Influenza B

- This bacteria can cause meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), epiglottitis (a severe throat infection), and other serious infections.
- Prior to the vaccine, 1 in 200 children were infected by this potentially fatal bacteria.
- Vaccine given at 2, 4, 6, and 12 months.

25

Haemophilus Influenza B



26

Polio

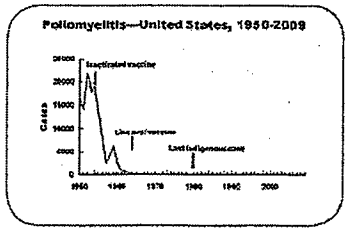
- Infects nerve cells and can result in paralysis.
- Vaccine can be given as shots or as oral doses.
- With continued vaccination, polio may be eradicated around the globe in the next 10 years.

27

Polio

28

Polio



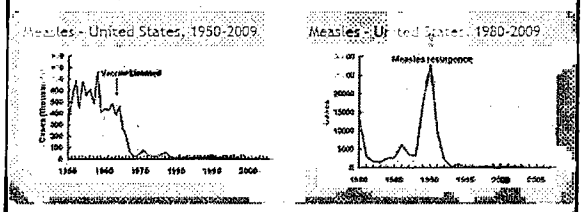
29

Measles

- The most deadly of all childhood rash/fever illnesses.
- Causes cough, runny nose, conjunctivitis (inflammation of the eye), rash, and fever.
- Complications include pneumonia, swelling of the brain, seizures, and death.
- Vaccine is given in combination with mumps and rubella at 12 months and 4 years.

30

Measles



31

Mumps

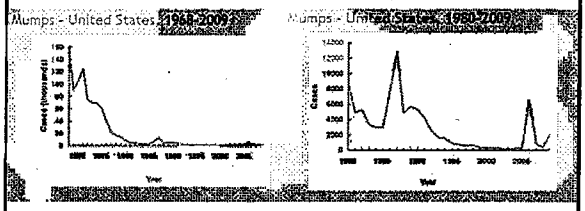
- Infection that causes generalized pain and fever and often causes swelling of glands in the neck.
- Can lead to more serious complications like deafness and death.
- Vaccine is given in combination with measles and rubella at 12 months and 4 years.

32

Mumps

33

Mumps



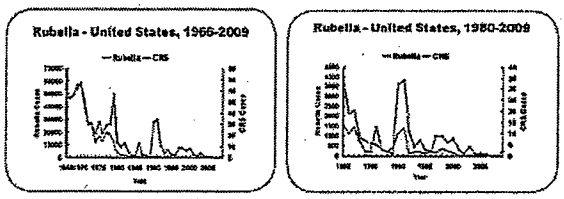
34

Rubella

- Infection that causes fever, rash, and swollen lymph.
- Can be very dangerous if acquired during pregnancy.
- Vaccine is given in combination with measles and mumps at 12 months and 4 years.

35

Rubella



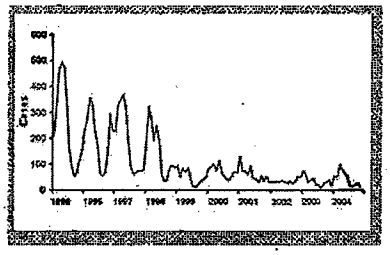
36

Varicella (chicken pox and shingles)

- The chicken pox are a VERY common infection in childhood that normally gets better on its own, but can require hospitalizations and have serious complications.
- Can reactivate as shingles which causes a very painful rash.
- Vaccine is given at 12 months and 4 years, and to adults to prevent shingles

37

Varicella (chicken pox and shingles)



Data from North Antelope Valley, CA

38

Varicella (chicken pox and shingles)

39

Questions?

40

Good reference websites

- www.cdc.gov/acip
- www.immunize.org
- www.vaccine.chop.edu
- www.ecbt.org
- www.immunizationinfo.org
- www.vaccinesafety.edu
- www.pkids.org

41

Ingredients to know about

- Egg proteins (important for the 1/200 people with an egg allergy)
- Antibiotics to which some people are allergic(neomycin)
- Yeast proteins
- Gelatin
- Methylmercury (all babies get 400 micrograms in first 6 months of life from breast milk alone)
- Aluminum, but less than is already in human blood
- Formaldehyde, but less than is already in human blood
- NO ALCOHOL OR ANTI-FREEZE

42

DR. DINICOLA 1/24/12
IMMUNIZATION

21

Testimony on S. 199- An act relating to immunization exemptions and immunization pilot program

Senate Committee on Health and Welfare

(January 24th, 2012)

I arrived in Vermont in June 1976 after training in Pittsburgh, PA. At that time we did not have child car seats, we did not have HIB vaccine and we did not have Varicella vaccine. The lack of these medical and safety advances resulted in many thousands of deaths, many 100s of thousands of hospitalizations and huge expense to our health care system in the USA.

Within the first few years in Vermont I knew of multiple infant deaths due to not being restrained properly in cars, deaths from HIB infections and even a few deaths from complications of Varicella (Chickenpox)

Now in 2012 we have come a long way. Properly restraint infants dying in car accidents, deaths from HIB meningitis and epiglottitis are almost unheard of. We have prevented many deaths. Yet despite the ability to prevent these childhood losses due to accidents and illness we had 10 deaths in 2010 in California and 10s of thousands of cases of pertussis in California alone a completely preventable disease.

We have developed excellent laws to require car restraints and vaccines for children especially in school settings and the results have been superb. One result is that many present day parents have not seen any of these conditions and coupled with major misinformation about vaccines, parents have opted to not vaccinate or under vaccinate their children. Our present law in Vermont allows for philosophically exemption from protecting their children and other children in the community. This has resulted in deaths from pertussis in California and other states and outbreaks of Measles, Mumps, and HIB infections, all preventable.

When parents do vaccinate their children as recommended and follow the recommended schedule, they should be able to reasonably expect that this will protect their children yet even though the vaccines are excellent, they are never 100% effective and HEARD immunity is necessary to keep our children safe. This is the KEY reason why all children should and must be vaccinated to enter school.

Some facts that are important:

- Vermont has repeatedly been the healthiest state in the country; much of this has been from our past history of very high vaccination rates. Last year Vermont along with Washington state were the worse in the country with over 5% "exemptions" reported. This means that 1 in 20 children are entering school either not vaccinated or partially vaccinated, a crucial number!

- Although other states have the philosophic exemption (19) only 7 states have the philosophic exemption that is "unlimited" like Vermont and these states notably are in the same class as Vermont for % of children not being vaccinated. Notably NH who repeatedly has the best vaccine rate in the country does not have a philosophic exemption.

- Today's vaccines are extremely safe and effective. The likelihood of a severe reaction from all the vaccines combined is about 0.0009% or about the same as being struck by lightening

- Vaccines are the most important advancement of medical science over the last 100 years resulting in the prevention of millions of deaths and 10 of millions of hospitalizations. Death from measles World wide alone over the last 10 years has been reduced by over 90% from 2,800,000/year to less than 280,000/year ALL due to measles vaccine!

- The California Pertussis experience is a dramatic exam of the disaster choosing to not vaccinate. In 2010 10 children died from Pertussis in California alone (there is usually less than that in the entire USA) and over 25,000 cases were documented all due to lack of immunization. Many of the young children who died, died even before they were old enough to get the vaccine because their school age siblings or parents were infected. Last year Vermont had the greatest number of cases of pertussis per 100,000 in the country and there is another outbreak in progress.

- **Children who enter school unvaccinated are a risk to themselves AND others. There are children in schools in Vermont who have medical conditions that do not allow them to be vaccinated and the unvaccinated classmates can infect them. When a parent in good faith gets all the recommended vaccines and their child fit into the 3-5% of "non responders" then they suffer from the lack of heard immunity.**

Most importantly Vermont has the tradition of protecting its children with excellent access to care, full access to all required vaccines, excellent child safety laws and protection of children in all settings.

It should be the responsibility of the state of Vermont to protect children against preventable diseases and like Seat belt laws, child abuse laws, lead exposure laws, smoking and drinking age laws and many more we should move to protect all children against these preventable diseases. Think about it, what if we had philosophic exemptions for seat belts, smoking, drinking, and child abuse laws?

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STATE OF VERMONT
SENATE COMMITTEE

Senate Committee on Health and Welfare

AGENDA

Room 17

February 7, 2012 - February 10, 2012

Tuesday, February 7, 2012

9:00 AM **Senate Floor**

\- **Chairs Meeting**

\- **Mental Health System of Care**

Walk Through

Rep. Ann Pugh, Chair, House Committee On Human Services

Katie McLinn, Legislative Counsel, Office of Legislative Council

Rebecca Heintz, Deputy Commissioner, Department of Mental Health

Wednesday, February 08, 2012

8:30 AM **S. 199 - An act relating to immunization exemptions and the immunization pilot program**

Harry Chen MD, Commissioner, Department of Health

9:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Overview

Patrick Flood, Commissioner, Department of Mental Health

9:30 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Community based programs reduce need for inpatient hospitalization

Nick Nichols, Policy Director, Department of Mental Health

10:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Capacity

Mary Moulton, Emergency Services, Washington County Mental Health Services

Margaret Joyal, Director of Outpatient Services, Washington County Mental Health Services

Robert Pierattini, MD, Fletcher Allen Health Care

Robert Althoff, MD, University Pediatrics at Fletcher Allen

Dave Ogden, FSA, Milliman

Peter Thomashow, MD, Central Vermont Medical Center

James Tautfest, RN, Central Vermont Medical Center

Tom Huebner, President, Rutland Regional Medical Center

Dr. W. Gordon Frankle, Rutland Regional Medical Center

Robert Simpson, Brattleboro Retreat

Peter Albert, Director of Government Affairs, Brattleboro Retreat

Kristy McLaughlin, Social Worker, Vermont State Hospital

Rebecca Heintz, Deputy Commissioner, Department of Mental Health

Thursday, February 09, 2012

8:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Committee Discussion

Rebecca Heintz, Deputy Commissioner, Department of Mental Health

Nick Nichols, Policy Director, Department of Mental Health

Katie McLinn, Legislative Counsel, Office of Legislative Council

9:00 AM **Bi-State Primary Care Association**

Susan Barrett, Director of Public Policy, Bi-State Primary Care Association

Grant Whitmer, Executive Director, Community Health Centers of Rutland

9:15 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Clinical Care Management System

Rebecca Heintz, Deputy Commissioner, Department of Mental Health

Jeff Rothenberg, Director of Mental Health Services, Clara Martin Center

Floyd Nease, Executive Director, Vermont Association for Mental Health and Addiction Recovery

Marty Robinson, Consumer

Friday, February 10, 2012

8:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Committee Discussion

Katie McLinn, Legislative Counsel, Office of Legislative Council

Rep. Anne Donahue, House Human Services Committee

8:30 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Administration's perspective on Vermont State Hospital replacement

Jeb Spaulding, Secretary, Secretary of the Administration

9:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Federal funding for state run facility

Catherine Benham, Associate Fiscal Officer, Legislative Joint Fiscal Office

Stephanie Barrett, Associate Fiscal Officer, Joint Fiscal Office

Suzanne Santarcangelo, Agency of Human Services

Rebecca Heintz, Deputy Commissioner, Department of Mental Health

Cornelius Hogan, Former Secretary, Agency of Human Services

11:00 AM **Committee Discussion**

VERMONT
DEPARTMENT OF HEALTH

Child Care and School Immunization Exemption Form

Vermont's Immunization law applies to any child or student in attendance at any licensed or registered child care, public or independent kindergarten, any elementary or secondary school and certain post-secondary schools. Before enrollment in child care or school, immunizations are required unless the child or student is exempt for medical, religious, or philosophical reasons. In order to claim an exemption this form needs to be completed, signed and returned to the child care or school.

Please note that students who claim an exemption may be kept out of school during the course of a disease outbreak. The reason for this is that such students will be at high risk for getting that disease and in-turn transmitting it to other students. The length of time a student is kept out of school will vary depending on the type of disease and the circumstances surrounding the outbreak.

The undersigned certify the following child or student is exempt from the vaccines as indicated below

Name: _____ _____ **Date of Birth:** ____/____/____
Last First

Vaccines: Check box to indicate exemption

- ☐ **DTaP/DTP (Diphtheria/Tetanus/Pertussis)**
- ☐ **MMR (Measles/Mumps/Rubella)**
- ☐ **Meningococcal**
- ☐ **Polio**
- ☐ **Varicella**
- ☐ **Td/Tdap (Tetanus/Diphtheria/Pertussis)**
- ☐ **Hepatitis B**

☐ **MEDICAL EXEMPTION**	**EXEMPTION: ☐ RELIGIOUS ☐ PHILOSOPHICAL**
Reason for exemption(s):_____ This exemption shall continue until : ____/____/_____	I request exemption from the immunization(s) indicated above because they conflict with my beliefs.
I certify that the parent/guardian has received information on the benefits and risks of immunization to their child as a condition for exempting their child from immunization for medical, religious or philosophical reasons. _____ (____)_____ **Print Name of Physician** **Telephone** _____ ___/___/_____ **Signature of Physician** **Date**	I certify that I have been provided with information on the benefits and risks of immunization and understand that if there is an outbreak of a vaccine-preventable disease my child has not been fully immunized against that my child may be at risk for disease and can be excluded from child care or school until the outbreak is over. _____ (____)_____ **Signature of Parent (or student if 18 yrs or older)** **Telephone** **Date** ___/___/_____

The Vermont Department of Health Immunization Program 108 Cherry Street Burlington, Vermont 05401
802-863-7638 or 1-800-464-4343 ext. 7638 healthvermont.gov

VERMONT
DEPARTMENT OF HEALTH

Child Care and School Immunization Exemption Form

DRAFT

The Vermont Department of Health Immunization Program 108 Cherry Street Burlington, Vermont 05401
802-863-7638 or 1-800-464-4343 ext. 7638 healthvermont.gov

HARRY CHEN 2/8/12 S.199

S.199 - Substitute the below for Sec. 1:

Sec. 1. 18 V.S.A. § 1122(a) is amended to read:

(a) A person may remain in school or in the child care facility without a required immunization:

(1) If the person, or in the case of a minor the person's parent or guardian presents a written statement from a licensed primary care health care practitioner, health clinic, or nurse that the person is in the process of being immunized. The person may continue to attend school or the child care facility as long as the immunization process is being accomplished;

(2) If a primary care health care practitioner, licensed to practice in Vermont, certifies in writing in a format approved by the commissioner that a specific immunization is or may be detrimental to the person's health or is not appropriate; provided that when it is determined that this particular vaccine is no longer contraindicated, the child will be required to have the vaccine;

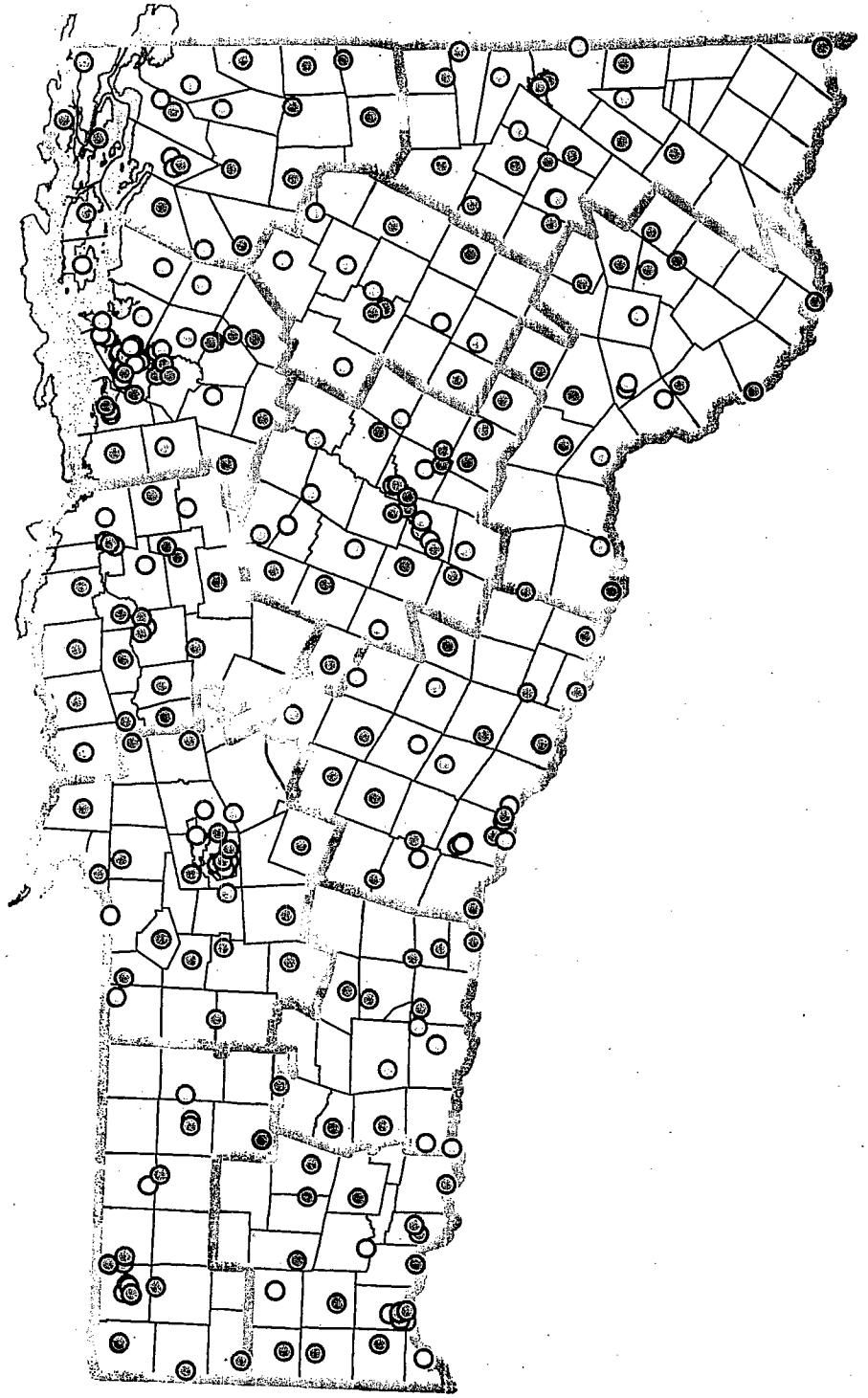
(3) If the person, or in the case of a minor the person's parent or guardian states in writing in a format approved by the commissioner that the person, parent, or guardian has religious beliefs or philosophical convictions opposed to immunization; and

(4) The form presented shall include a statement signed by a licensed primary care health care practitioner stating that he or she provided the person, or in the case of a minor the person's parent or guardian, with information about the benefits and risks of immunization to the child. The form may be signed by the licensed primary care health care practitioner at any time prior to the enrollment of the child in registered child care or school. Photocopies of the signed form shall be accepted in lieu of the original form.

(b) The health department may provide by rule for further exemptions to immunization based upon sound medical practice.

(c) A licensed primary care health care practitioner who, in good faith, signs the statement provided for in subsection (a) of this section is immune from civil liability for providing the signature.

HAZELY CHEN 2/6/12 S.199



VERMONT

DEPARTMENT OF HEALTH

VT School Immunization Data
Percent of Kindergarten Students with Philosophical Exemptions

Philosophical IZ Exemptions - % of K

2010-2011

- 0%
- 0.01 - 4.38%
- within 1% of state rate (5.38%)
- 6.39% - 10%
- > 10%
- Vermont Health Districts
- Vermont Towns

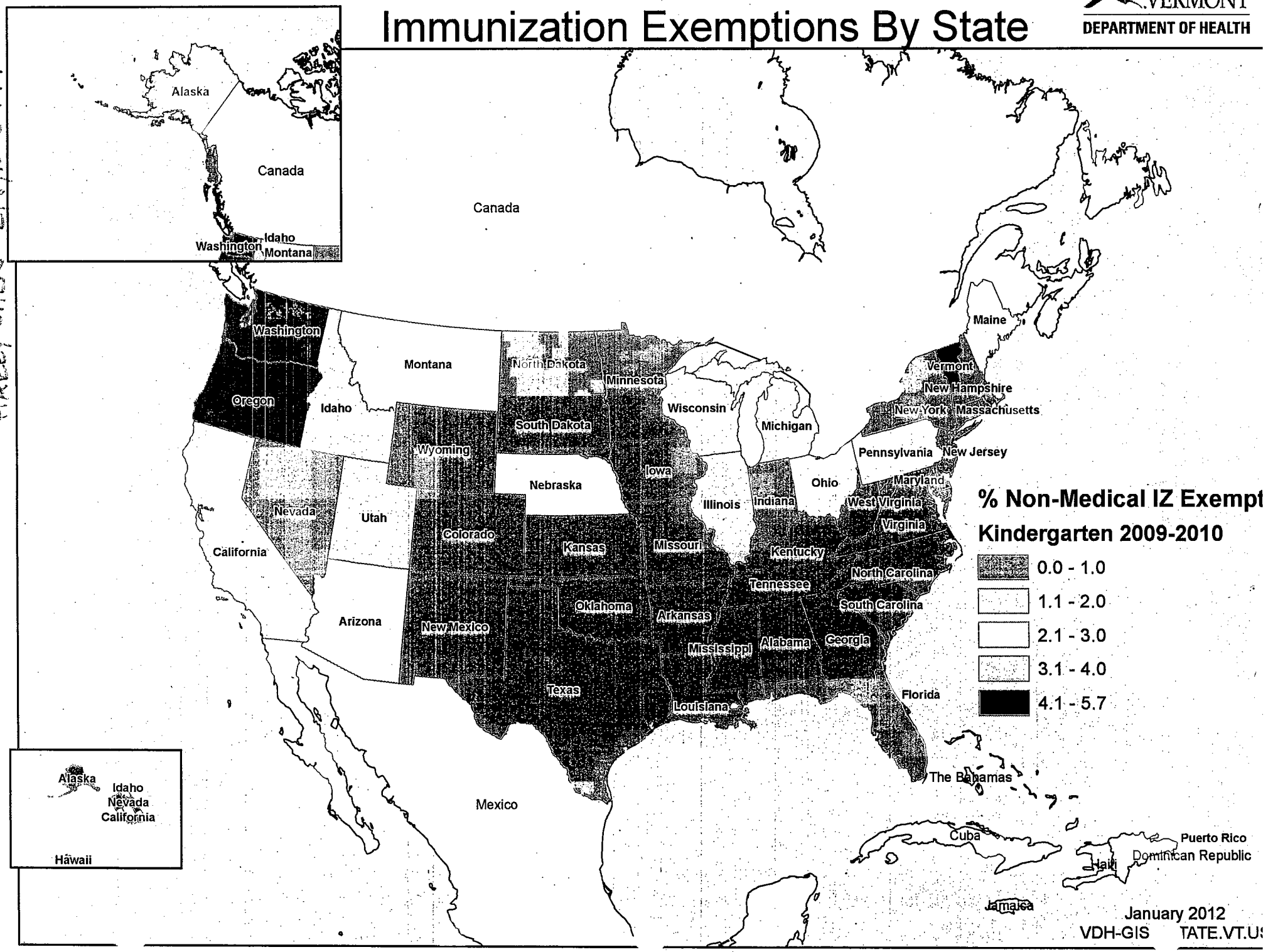
DRAFT

VDH-GIS@STATE.VT.US

FEBRUARY 1, 2012

Percent School Non-Medical Immunization Exemptions By State

VERMONT DEPARTMENT OF HEALTH



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STATE OF VERMONT
SENATE COMMITTEE

Senate Committee on Health and Welfare

AGENDA

Room 17

February 28, 2012 - March 2, 2012

Last Updated 3/2/2012 11:39 AM

Tuesday, February 28, 2012

9:00 AM — **S. 199 - An act relating to immunization exemptions and the immunization pilot program**

Katie McLinn, Legislative Counsel, Office of Legislative Council

NO HANDOUTS

9:15 AM — **S. 207 - An act relating to preconditions for Green Mountain Care implementation**

Stephen Kimbell, Commissioner, Department of Banking, Insurance, Securities & Health Care Administration

9:30 AM — **Senate Floor**

After Floor — **H. 630 - An act relating to reforming Vermont's mental health system**

Katie McLinn, Legislative Counsel, Office of Legislative Council

Nick Nichols, Policy Director, Department of Mental Health

Laura Ziegler, Concerned Citizen

Megan O'Donnell, Assistant General Counsel, Fletcher Allen Health Care

Jill Olson, VP Policy and Operations, Vermont Association of Hospitals and Health Systems

11:30 AM — **H. 755 - An act relating to extending the deadline for adoption of certain health department rules**

Harry Chen MD, Commissioner, Department of Health

Wednesday, February 29, 2012

9:00 AM **H. 630 - An act relating to reforming Vermont's mental health system**

Ombudsman Amendment

Robert Appel, Executive Director, Human Rights Commission

Ed Paquin, Director, Vermont Coalition for Disability Rights

A.J. Ruben, Supervising Attorney, Vermont Coalition for Disability Rights

Patrick Flood, Commissioner, Department of Mental Health

Trinka Kerr, Health Care Ombudsman

Jill Olson, VP Policy and Operations, Vermont Association of Hospitals and Health Systems

H. 630 - An act relating to reforming Vermont's mental health system

Amendments

Katie McLinn, Legislative Counsel, Office of Legislative Council

Nick Nichols, Policy Director, Department of Mental Health

Laura Ziegler, Concerned Citizen

Sen. Richard Westman, Lamoille County

Floyd Nease, Executive Director, Vermont Association for Mental Health and Addiction Recovery

Peter Albert, Director of Government Affairs, Brattleboro Retreat

Jill Olson, VP Policy and Operations, Vermont Association of Hospitals and Health Systems

Thursday, March 01, 2012

9:00 AM **S. 223 - An act relating to extending health insurance coverage for autism spectrum disorders**

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

Robin Lunge, Director of Health Care Reform, Agency of Administration

Christine Oliver, Deputy Secretary, Agency of Human Services

Katie McLinn, Legislative Counsel, Office of Legislative Council

Judith Ursitti, Regional Director, National Autism Speaks Organization

Samuel Abel-Palmer, Staff Attorney, Disability Law Project

Leigh Tofferi, Director of Government Relations, Blue Cross/Blue Shield of Vermont

Susan Gretkowski, Lobbyist, MVP Healthcare

Jeanne Kennedy, Lobbyist, Cigna Health Care

Amy Cohen, Clinical Director Autism Spectrum Disorder, Howard Center

10:45 AM **S. 89 - An act relating to Medicaid for Working Persons with Disabilities**

Mark Larson, Commissioner, Department of Vermont Health Access (DVHA)

Sam Liss, Chair, Vermont Statewide Independent Living Council

Karen Lafayette, Lobbyist, Vermont Coalition for Disability Rights

Trinka Kerr, Health Care Ombudsman

10:45 AM **S. 222 - An act relating to cost-sharing for employer-sponsored insurance assistance plans**

Mark Larson, Commissioner, Department of Vermont Health Access (DVHA)

Lila Richardson, Staff Attorney, Office of Vermont Health Care Ombudsman

Friday, March 02, 2012

9:00 AM **S. 223 - An act relating to extending health insurance coverage for autism spectrum disorders**

Christine Oliver, Deputy Secretary, Agency of Human Services

Nolan Langweil, Fiscal Analyst, Joint Fiscal Office

Susan Gretkowski, Lobbyist, MVP

Charles Storrow, Lobbyist, Blue Cross/Blue Shield of Vermont

Margaret Laggis, Lobbyist, America's Health Insurance Plans (AHIP)

Julie Tessler, Director, Vermont Council of Developmental and Mental Health Services

Katie McLinn, Legislative Counsel, Office of Legislative Council

10:15 AM **S. 200 - An act relating to the reporting requirements of health insurers**

Kevin Goddard, Vice President of External Affairs, Blue Cross/Blue Shield of Vermont

Katie McLinn, Legislative Counsel, Office of Legislative Council

Jeanne Kennedy, Lobbyist, Cigna Health Care

Clifford Peterson, General Counsel, Department of Banking, Insurance, Securities & Health Care Administration

Cassandra Gekas, Health Care Advocate, VPIRG

Margaret Laggis, Lobbyist, America's Health Insurance Plans (AHIP)

Charles Storrow, Lobbyist, Blue Cross/Blue Shield of Vermont

11:30 AM **Senate Floor**

Senate Committee on Health and Welfare
RECORD OF ACTION ON BILL

H_____ S 199 Title: Immunization exemptions & pilot programs
Sponsor: MULLIN

Date Voted Out 2/28/12 Date Reported _____ Reporter MULLIN

Please attach a copy of the final draft as voted out

	VOTES OF THE COMMITTEE															
MEMBERS	BILL VOTED OUT		VOTE NO. 1		VOTE NO. 2		VOTE NO. 3		VOTE NO. 4		VOTE NO. 5		VOTE NO. 6		VOTE NO. 7	
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Ayer	X															
Fox																
Miller	X															
Mullin	X															
Pollina		X														

Please List Votes Numerically

TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred Senate Bill No. 199 entitled "An act relating to immunization exemptions and the immunization pilot program" respectfully reports that it has considered the same and recommends that the bill be amended by striking out Sec. 1 in its entirety and inserting in lieu thereof the following:

Sec. 1a. 18 V.S.A. § 1120 is amended to read:

§ 1120. DEFINITIONS

As used in this subchapter:

* * *

(3) "Primary care" means health services provided by health care professionals specifically trained for and skilled in first-contact and continuing care for individuals with signs, symptoms, or health concerns, not limited by problem origin, organ system, or diagnosis, and shall include family planning, prenatal care, and mental health and substance abuse treatment.

(4) "Primary care provider" means:

(A) a physician licensed pursuant to 26 V.S.A. chapter 31 who practices primary care;

(B) an advanced practice registered nurse licensed pursuant to 26 V.S.A. chapter 28 and certified as a nurse practitioner who practices primary care;

(C) a physician assistant licensed pursuant to 26 V.S.A. chapter 31 who practices primary care; or

(D) a naturopathic physician licensed pursuant to 26 V.S.A. chapter 81 who practices primary care.

Sec. 1b. 18 V.S.A. § 1122 is amended to read:

§ 1122. EXEMPTIONS

(a) ~~A~~ Notwithstanding section 1121 of this title, a person may remain in school or in the child care facility without a required immunization:

(1) If the person~~,~~ or, in the case of a minor, the person's parent or guardian presents a written statement from a licensed ~~health care practitioner,~~ primary care provider or health clinic~~, or nurse~~ that the person is in the process of being immunized. The person may continue to attend school or the child care facility as long as the immunization process is being accomplished;

(2) If a ~~health care practitioner~~ primary care provider, licensed to practice in Vermont, certifies in writing in a format described in subsection (c) of this section that a specific immunization is or may be detrimental to the person's health or is not appropriate, provided that if the vaccine is determined to be neither detrimental nor inappropriate to the person's health at some future date, the person shall be required to receive the vaccine; or

(3) If the person, or in the case of a minor the person's parent or guardian states in writing in a format described in subsection (c) of this section

that the person, parent, or guardian has religious beliefs or philosophical convictions opposed to immunization.

(b) The health department may provide by rule for further exemptions to immunization based upon sound medical practice.

(c) In the event an exemption is claimed under subdivision (a)(2) or (a)(3) of this section, an immunization exemption form shall be presented to a person's school or child care facility at any time prior to enrollment. The immunization exemption form shall be created by the Vermont department of health, and shall be signed by a licensed primary care provider stating that the provider presented the person, or in the case of a minor, the person's parent or guardian, with information regarding the benefits of immunization and the risks to the person and community for failure to immunize. Photocopies of the signed immunization exemption form shall be accepted in the absence of the original form.

(d) A licensed primary care provider who signs an immunization exemption form in good faith pursuant to subsection (c) of this section shall be immune for civil liability for providing a signature.

(Committee vote: _____)

_____

Senator [surname]

FOR THE COMMITTEE

"There are unanswered questions about vaccine safety. . . .
No one should be threatened by the pursuit of this knowledge."

—Bernadine Healy, M.D., former director, National Institutes of Health (NIH), and current health editor, *U.S. News & World Report*

VACCINE EPIDEMIC

How Corporate Greed, Biased Science, and Coercive Government Threaten Our Human Rights, Our Health, and Our Children

Edited by

Louise Kuo Habakus, M.A.

Director, Center for Personal Rights

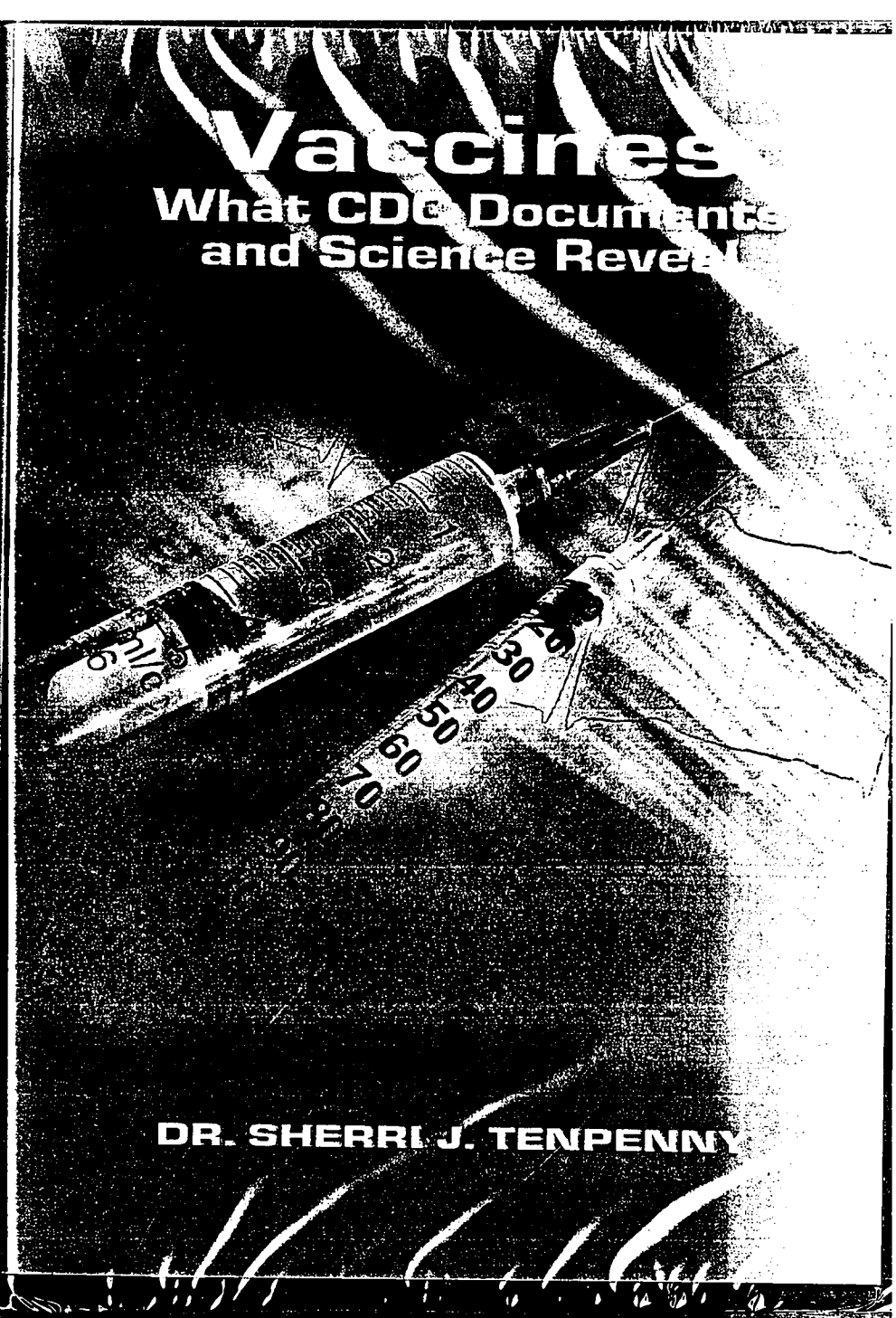
and

Mary Holland, J.D.

Research Scholar, NYU School of Law

Vaccines

What CDC Documents and Science Reveal



DR. SHERRI J. TENPENNY