

Capitol Hill Briefing  
Thursday, November 7, 2013

***The 1986 National Childhood Vaccine  
Injury Act  
and its  
Vaccine Injury Compensation Program***

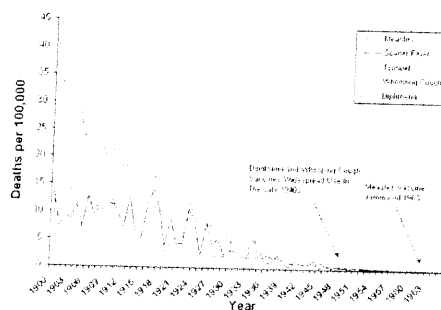
*By Mary Holland  
Research Scholar, NYU Law School  
Co-Founder and Board Member, Elizabeth Birt  
Center for Autism Law and Advocacy (EBCALA)*

**Agenda for Briefing**

- I. Context of US vaccine policy
- II. Children's health today
- III. The Vaccine Injury Compensation Program; Video; Autism; Options
- IV. The Faces of vaccine injury:  
Gardasil girls

**I. U.S. Vaccination Law and Policy**

**Large Drops in Disease Deaths Before Vaccines Introduced**



CDC's Vital Statistics of the United States (VSUS), [www.cdc.gov/vs](http://www.cdc.gov/vs)

[illegible]

Example 1: A company has 100 employees. 60 are men and 40 are women. What is the probability of selecting a man?

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CDC 2010 vaccine schedule: [www.tinyurl.com/69uo5al](http://www.tinyurl.com/69uo5al)

State Immunization Manuals  
One way to give 7 doses (if needed)  
at one visit

One way to give 7 doses (if needed) at one visit

The default system is provided for MMR, including combined with Hib and/or with HepB, and PCV7.

Colorado Immunization Manual, pg. 28, [www.coloradoimmunization.com/y3/infod](http://www.coloradoimmunization.com/y3/infod)

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## How Did We Get Here?

- Two legal structures enabled this:
  - State laws to compel vaccination
  - The 1986 Act relieving manufacturers and doctors of almost all liability in the event of injury

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## Legal Basis for Vaccine Mandates in U.S.

### 1905 Jacobson v. MA

- Widespread smallpox
- Contagious, airborne disease
- Often fatal disease
- One vaccine
- Adults only
- \$3 fine for non-compliance (\$114 today) to state

### Present Day

- No widespread disease
- Many diseases are not easily contagious
- 70 doses of 16 vaccines
- Kids only
- Denial of schooling for non-compliance
  - Medical and religious exemptions subject to review

Basis for vaccine mandates:  
Freedom of the individual must sometimes be subordinated to common welfare

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## II. CHILDHOOD IN AMERICA

### THE "NEW NORMAL"

1 in 3	Overweight
1 in 6	Learning Disabilities
1 in 9	Asthma
1 in 10	ADHD
1 in 12	Food Allergies
1 in 50	Autism spectrum
3-5 in 100	Birth Defects
1 in 100	Seizures
1 in 450	Diabetes
1 in 6,000	Cancer

50% of children have a chronic health condition

[illegible]

## Childhood Health

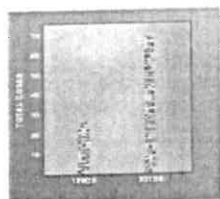
### Infant Mortality Statistics

1 in 144 American babies dies before age one.  
We trail most peer countries and many poorer ones.

<u>YEAR</u>	<u>USA INFANT MORTALITY RANK</u>
1950 (before mass immunization)	3rd
1986	17th
1995	23rd
2000	31st
2012	50th

We lag behind United Kingdom, Australia, Canada, Macau, Anguilla, Andorra, Slovenia, Faroe Islands, Cuba and Belarus.  
<https://www.euro.who.int/publications-the-world-factbook/en/order/2019/enk.html>, America's Health Rankings,  
<http://www.americashealthrankings.org.aspx>

## Vaccine-autism correlation?



## 1 in 50 Children

The federal government has failed to respond to the salmon epidemic for more than 10 years.

Which Road Matters  
 The Race Conference

In 1980s, autism incidence 4-5 in 10,000

Today, 1 in 50 by parental report (CDC)

Rise not explained simply by more awareness and broader diagnostic criteria

## What is Autism?

Currently defined by the DSM-IV 299.00

- Autistic Disorder: impairs
  - Social interaction
  - Communication
  - Stereotyped patterns of behavior
- Onset before age 3




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## Draw Shop Video

- VICP and autism video

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## III. 1986 Act and the VICP

Three objectives, to:

- Stabilize the vaccine supply by protecting industry and healthcare workers from liability
- Compensate the injured
- Make safer vaccines

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### The 1986 Act

- Congress intended no-fault, swift, generous, non-adversarial system
- Acknowledges vaccines are “unavoidably unsafe”
- Acknowledges vaccines will injure and cause death
- Provides limited recourse to civil court depriving people of 7<sup>th</sup> Amendment right to civil jury trials
- Takes away right to informed consent

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### The 1986 Act's Pledge

- Do safety research to reduce vaccine injuries
- Update table injuries
- Resolve claims within a year
- Be non-adversarial
- Close calls go to petitioners – “more likely than not”
- Recognition that there might be overcompensation

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### The 1986 Act's Failed Pledge

- Little Safety Research
- Almost No New Injuries Added to Table
- Forum is exceptionally adversarial
- 90% of claims are now “off-table,” requiring proof of causation
- 80% of claimants who file lose

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## Vaccine Injury Table

As of Oct. 17, 2013, approximately  
\$2.8 billion has been paid for 3,400  
compensated cases

### ASSUMED ADVERSE EVENTS under 10% of cases

Death	Chronic Arthritis
Encephalopathy	Vaccine-Strain Measles
Anaphylaxis	Vaccine-Strain Polio
Seizure disorder	Paralytic Polio

### ADVERSE EVENTS CONCEDED IN LITIGATION over 90% of cases

Juvenile diabetes, ADHD, Rheumatoid arthritis, Asthma, Severe allergies in addition to those above

HHS statistics: <http://www.hhs.gov/vaccine/injury/compensation/statistics/reports.html#State>  
Vaccine Injury Table: <http://www.hhs.gov/vaccine/injury/compensation/vaccine-injury-table.html>

## Study on Autism among VICP Compensated Cases

Pace Environmental Law Review

Volume 26  
Issue 1 Winter 2013

5-10 2013

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

Mary Holland  
2013 Volume of Law, Medicine & Bioethics

Linda Conner

Robert McClellan

Lisa Cohen

## Unanswered Questions

- Found 83 cases of reported autism among compensated cases of vaccine injury
- 21 are in published court decisions; 62 from settlements

## Descriptions of Vaccine-induced Autism in published VICP cases

Published Case Chart		
Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
1. <i>Alger v. Sec'y of Health &amp; Human Servs.</i>	1990 WL 293109, at *1 (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. <i>Sorenson v. Sec'y of Health &amp; Human Servs.</i>	1990 WL 296191, at *1 (Cl. Ct. Dec. 8, 1990).	"Petitioner further maintain that the injuries resulted in permanent disabilities involving significant developmental delay, moderate autistic characteristics, and mental retardation."
3. <i>Klounert v. Sec'y of Health &amp; Human Servs.</i>	1991 WL 20664, at *2, *4 (Cl. Ct. Feb. 20, 1991).	"Today he has a seizure disorder which is under control and a condition known as over feeding, similar in some respects to autism. . . . As a sequel to the encephalopathy, Wes Ian Klounert suffered complications for more than six months after the administration of the DTP vaccine, and he continues to suffer from these complications, which have developed into a residual seizure disorder and autistic tendencies."
4. <i>Connor v. Sec'y of Health &amp; Human Servs.</i>	1991 WL 12618, at *4 (Cl. Ct. July 3, 1991).	"Respondent's report . . . suggests vaguely . . . that Kenny's problems may be attributed in part to other causes such as a family history of epilepsy, autism and toxoid hypersensitivity. Dr. Spien 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."

## Descriptions of Vaccine-induced Autism in published VICP cases

Published Case Chart		
Published Case Name	Case Citation	Language Suggesting Autism or Autism-like Symptoms
20. <i>Bank v. Sec'y of Health &amp; Human Servs.</i>	2007 U.S. Claims LEXIS 254, at *54 (Fed. Cl. July 20, 2007).	"Duke's (DDM) vaccine 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 precise sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay."
21. <i>Chad Dwyer v. Sec'y of Health &amp; Human Servs.</i>	2010 WL 3348634, at *1 (Fed. Cl. July 21, 2010).	"Respondent has conceded that petitioners are entitled to compensation due to the significant aggravation of Child Doe's pre-existing mitochondrial disorder based on an MMR vaccine. Table pre-symptomatic injury of encephalopathy, which eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequel."

Kimberly Sue Leteure, compensated by VICP for encephalopathy (with seizures and autism)





### Omnibus Autism Proceeding

- 2002-2010 in VICP
- Over 5,000 claims filed
- Tested two theories:
  - Mercury-induced autism
  - Measles-mumps-rubella-induced autism
- 6 test cases heard
- Special Masters ruled against all cases; two MMR appeals upheld

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### The Yates Hazlehurst Dismissal



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Michelle Cedillo, **NOT** compensated for autism (with encephalopathy and seizures)



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## Dr. Zimmerman's Second Medical Opinion Letter

Dr. Zimmerman's second medical opinion. The child was diagnosed and treated for autism spectrum disorder (ASD) and epilepsy. The child was also diagnosed with intellectual disability (ID) and was found to have a mild to moderate degree of encephalopathy.

The following are my comments regarding the child's condition:

1. The child's symptoms are consistent with a diagnosis of autism spectrum disorder (ASD) and epilepsy. The child's symptoms are consistent with a diagnosis of intellectual disability (ID) and encephalopathy. The child's symptoms are consistent with a diagnosis of mild to moderate degree of encephalopathy.
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I would like to express my sincere appreciation for the opportunity to provide this second medical opinion.

Dr. Zimmerman  
 Dr. Zimmerman, MD  
 Dr. Zimmerman, MD  
 Dr. Zimmerman, MD  
 Dr. Zimmerman, MD

## DOJ Representations to the Court of Appeals for the Federal Circuit

1. The DOJ represents that the child was diagnosed with autism spectrum disorder (ASD) and epilepsy. The child was also diagnosed with intellectual disability (ID) and was found to have a mild to moderate degree of encephalopathy.
2. The DOJ represents that the child's symptoms are consistent with a diagnosis of autism spectrum disorder (ASD) and epilepsy. The child's symptoms are consistent with a diagnosis of intellectual disability (ID) and encephalopathy. The child's symptoms are consistent with a diagnosis of mild to moderate degree of encephalopathy.
3. The DOJ represents that the child's symptoms are consistent with a diagnosis of autism spectrum disorder (ASD) and epilepsy. The child's symptoms are consistent with a diagnosis of intellectual disability (ID) and encephalopathy. The child's symptoms are consistent with a diagnosis of mild to moderate degree of encephalopathy.
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10. The DOJ represents that the child's symptoms are consistent with a diagnosis of autism spectrum disorder (ASD) and epilepsy. The child's symptoms are consistent with a diagnosis of intellectual disability (ID) and encephalopathy. The child's symptoms are consistent with a diagnosis of mild to moderate degree of encephalopathy.

Rolf Hazlehurst, father of Yates, one of the petitioners in the Omnibus Autism Proceeding. Son NOT compensated for autism (with seizures and encephalopathy).



## What's Wrong with the VICP?

- No alternative venue
- No judicial independence
- 90% of cases "off table"
- 80% of claims lose
- Lack of equality of arms
- 3-year statute of limitations
- Lawyers not timely paid
- Experts demeaned and not timely paid
- Delays of 10 years and more
- No design defect claims
- Conflicts of interest between vaccine promotion and compensation
- Little transparency
- People don't know VICP exists
- No rules of evidence
- No rules of civil procedure
- No discovery
- No jury trials
- Almost no recourse to civil court
- Very little science available

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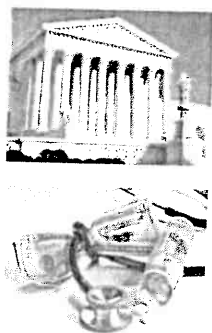
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## "All Profits, No Liability"

*Bruesewitz v. Wyeth*

2011 Supreme Court decision

- No claims for vaccine defect may be filed in any court
- YOYO
- For 99% of claims, there will be no recourse to civil court.




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Hannah Bruesewitz, NOT compensated for DPT-induced encephalopathy and seizures (with autism)




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## Dr. Julie Gerberding, a "Poster Child" of Vaccine Conflicts of Interest




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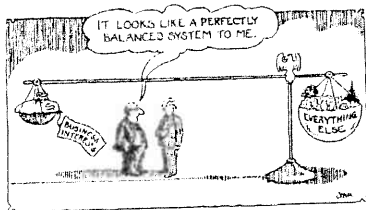
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## Justice in the VICP?




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## Policy Options for the 1986 Act

- Do nothing (done)
- Tinker at edges (done)
- Make the VICP optional (like 9/11 Commission)
- Give limited liability protection (only 7 vaccines from 1986)
- Repeal the Act
  - Give access to civil courts
  - Make manufacturers liable
  - Revert to state informed consent laws
  - Overturn *Bruesewitz v. Wyeth*
- Create a federal right of exemption (as in UK, Canada and other countries)
- Both repeal Act and create federal exemption right

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## Congressman Dan Burton



We have gone from one in 10,000 children with autism to one in 88. It is worse than an epidemic, it is an absolute disaster.

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## Congress off to a good start in 2012



Has the CDC done a study comparing vaccinated children with unvaccinated children yet?



We have never studied vaccinated versus unvaccinated.

DR. BOYLE

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## IV. The Faces behind Vaccine Injury: Gardasil Girls

- Gardasil Girls

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### What You Can Do

- Ask your Congress Member to Come to the OGR Hearing on December 4, 2013.
- Reach out for more information.
- Thank you.

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