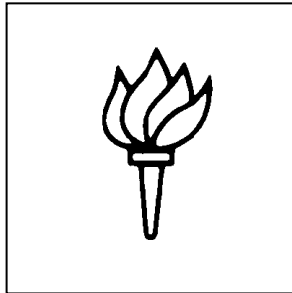


# NEW YORK UNIVERSITY SCHOOL OF LAW

**PUBLIC LAW & LEGAL THEORY RESEARCH PAPER SERIES  
WORKING PAPER NO. 10-64**



Reconsidering Compulsory Childhood Vaccination

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September 2010

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September 10, 2010

### 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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<sup>1</sup> 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.

## Reconsidering Compulsory Childhood Vaccination

INTRODUCTION .....	2
I. State Police Power to Compel Childhood Vaccination .....	4
A. Judicial Decisions before <i>Jacobson v. Massachusetts</i> .....	4
B. <i>Jacobson v. Massachusetts</i> .....	6
C. <i>Jacobson's</i> Application .....	9
1. <i>Zucht v. King</i> : Applying <i>Jacobson</i> to School Mandates .....	10
2. Early Interpretation of <i>Jacobson</i> .....	11
3. Later Interpretation of <i>Jacobson</i> .....	12
D. Scholarly Interpretation of <i>Jacobson's</i> Legacy .....	14
E. Legal Developments Leading to the 1986 Law .....	15
1. Advisory Committee on Immunization Practices (ACIP) ..	16
2. Vaccine Injury Litigation .....	17
II. The 1986 Law .....	21
III. The Effects of U.S. Vaccine Laws .....	24
A. Inadequate Safety .....	26
1. Inadequate Vaccine Testing .....	27
2. Dangerous Vaccine Additives .....	28
3. Failure to Screen Vulnerable Subjects .....	29
4. Insufficient Incentives and Funding for Vaccine Safety .....	29
5. Government Discouragement of Public Discourse .....	30
B. Failure to Compensate Vaccine Injury Victims Generously .....	31
C. Failure to Provide Accurate Information .....	33
D. Conflicts of Interest and Troubling Aspects of the Vaccine Ind .....	34
1. Conflicts of Interest .....	34
2. The Pharmaceutical Industry .....	36
E. Children's Health Problems .....	40
IV. Reinterpreting <i>Jacobson</i> and Amending the 1986 Law .....	41
CONCLUSION .....	44

*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.<sup>2</sup>*

## **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.<sup>3</sup> More than ten thousand people have sought compensation for vaccine injury to date.<sup>4</sup> 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.<sup>5</sup> 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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<sup>2</sup> *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3rd Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

<sup>3</sup> See National Network for Immunization, State Requirements, <http://www.immunizationinfo.org/vaccines/state-requirements>.

<sup>4</sup> National Vaccine Injury Compensation Program, Statistics Report, Health Resources and Services Administration (July 14, 2010), [http://www.hrsa.gov/vaccinecompensation/statistics\\_report.htm](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).

<sup>5</sup> *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.<sup>6</sup> These dramatic declines were likely due to better sanitation, cleaner water, better overall nutrition and the availability of antibiotic and antiviral medicines.<sup>7</sup>

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.<sup>8</sup> 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.<sup>9</sup> *Zucht* upheld vaccination mandates as a condition for school attendance.<sup>10</sup> And the 1986 Law created the modern national vaccine program: the infrastructure for mass childhood vaccination;<sup>11</sup> insulation of vaccine manufacturers and medical practitioners from ordinary tort liability;<sup>12</sup> removal of the right to accurate and complete information;<sup>13</sup> establishment of a program to compensate vaccine-injured victims;<sup>14</sup> and the obligation to make safer vaccines.<sup>15</sup>

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.<sup>16</sup> Like those sectors, the vaccine industry has largely 'captured' its regulators; the

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<sup>6</sup> 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).

<sup>7</sup> *Id.* at *Comment* section ("During the first 8 decades of the 20<sup>th</sup> 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.")

<sup>8</sup> 42 U.S.C. § 300aa-1 *et seq.* (2010)

<sup>9</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>10</sup> *Zucht v. King*, 260 U.S. 174 (1922).

<sup>11</sup> National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-2 (1986 Law).

<sup>12</sup> *Id.* § 300aa-11.

<sup>13</sup> *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).

<sup>14</sup> *Id.* § 300aa-10.

<sup>15</sup> *Id.* § 300aa-27.

<sup>16</sup> 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](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.<sup>17</sup> 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 20<sup>th</sup> century. During the 19<sup>th</sup> century, movement from the countryside to cities, with poor housing and inadequate sanitation and drinking water, spurred outbreaks of infectious disease.<sup>18</sup> 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).

<sup>17</sup> *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).

<sup>18</sup> *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.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup>

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.<sup>24</sup> 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.<sup>25</sup> 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."<sup>26</sup> In 1900, a California court established that no vaccination mandate could be applied in a racially

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<sup>19</sup> *Id.* at 621.

<sup>20</sup> *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))).

<sup>21</sup> *Id.*

<sup>22</sup> 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).

<sup>23</sup> 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.").

<sup>24</sup> *Duffield v. Williamsport Sch. Dist.*, 29 A. 742 (Pa. 1894).

<sup>25</sup> *Cox v. Bd. of Educ.*, 60 P. 1013, 1020 (Utah 1900).

<sup>26</sup> *Freeman v. Zimmerman*, 90 N.W. 783, 784 (Minn. 1902).

discriminatory manner because it would violate the equal protection clause of the 14<sup>th</sup> Amendment to the Constitution.<sup>27</sup>

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.<sup>28</sup>

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,<sup>29</sup> mandates for certain categories of adults, such as healthcare workers,<sup>30</sup> and public health emergency acts with vaccination provisions in many states.<sup>31</sup> Decided by the Supreme Court in

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<sup>27</sup> *Wong Wai v. Williamson*, 103 F. 1 (N.D. Cal. 1900).

<sup>28</sup> *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).

<sup>29</sup> 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.").

<sup>30</sup> 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>.

<sup>31</sup> 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).<sup>32</sup> 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 5<sup>th</sup> and 14<sup>th</sup> Amendments.<sup>33</sup> 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."<sup>34</sup> 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."<sup>35</sup> The Court found that the regulation did not violate the 14<sup>th</sup> Amendment because it was "applicable equally to all in like condition."<sup>36</sup> 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.<sup>37</sup>

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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<sup>32</sup> 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](http://www.bls.gov/data/inflation_calculator.htm).

<sup>33</sup> "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.

<sup>34</sup> *Jacobson*, 197 U.S. at 27.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 29-30.

non-compliance. The Court’s paradigm was clear: a mandate in “an emergency;”<sup>38</sup> when there was “imminent danger;”<sup>39</sup> when “an epidemic of disease...threatens the safety of [society’s] members;”<sup>40</sup> when there was “the pressure of great dangers”<sup>41</sup> and an “epidemic that imperiled an entire population.”<sup>42</sup>

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.<sup>43</sup>

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.”<sup>44</sup> 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.<sup>45</sup>

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.”<sup>46</sup> 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.”<sup>47</sup>

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.<sup>48</sup> Because of *Jacobson*, medical exemptions exist in all 50 states.<sup>49</sup> The Court

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<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 29.

<sup>40</sup> *Id.* at 27.

<sup>41</sup> *Id.* at 28.

<sup>42</sup> *Id.* at 31.

<sup>43</sup> *Id.* at 28 (*citing* Wis., Minn., & Pac. R.R. v. *Jacobson*, 179 U.S. 287 (1900)).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 29.

<sup>46</sup> *Id.* at 31.

<sup>47</sup> *Id.* at 38.

<sup>48</sup> *Id.* at 39.

<sup>49</sup> 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.”<sup>50</sup> 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.”<sup>51</sup> It made clear that no law should be interpreted in practice to be “cruel and inhuman in the last degree.”<sup>52</sup>

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.<sup>53</sup> 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.<sup>54</sup> These decisions found that statutes that did not include medical exemptions had to be read to contain them.<sup>55</sup> The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.<sup>56</sup>

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.<sup>57</sup> 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*.”).

<sup>50</sup> *Jacobson*, 197 U.S. at 30.

<sup>51</sup> *Id.* at 39.

<sup>52</sup> *Id.*

<sup>53</sup> *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).

<sup>54</sup> *O’Bannon*, 119 S.W. at 427.

<sup>55</sup> *McFadden*, 104 P. at 216.

<sup>56</sup> *Hammond*, 80 N.E. at 651.

<sup>57</sup> *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.”<sup>58</sup> The court deferred to municipal authorities on public health.<sup>59</sup>

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.”<sup>60</sup> 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.<sup>61</sup> In a cursory, unanimous decision, the Court cited to *Jacobson* as settling that compulsory vaccination may be a requirement of public school admission.<sup>62</sup> The Court denied the petitioner’s claim of infringement of her 5<sup>th</sup> and 14<sup>th</sup> Amendment rights based on *Jacobson*.<sup>63</sup> It considered, though, that the law might have been administered in a way that violated her rights.<sup>64</sup> 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.”<sup>65</sup> 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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<sup>58</sup> *Id.* at 323.

<sup>59</sup> *Id.*

<sup>60</sup> *Bd. of Trs. v. McMurtry*, 184 S.W. 390, 394 (Ky. 1916).

<sup>61</sup> *Zucht*, 260 U.S. at 176.

<sup>62</sup> *Id.* at 176.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 177.

<sup>65</sup> *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.<sup>66</sup> 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."<sup>67</sup>

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."<sup>68</sup> 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."<sup>69</sup> 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.<sup>70</sup>

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.<sup>71</sup> This Texas court majority

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<sup>66</sup> *Rhea v. Bd. of Educ.*, 171 N.W. 103 (N.D. 1919).

<sup>67</sup> *Id.* at 106.

<sup>68</sup> *Id.* at 107 (Birdzell, J., concurring).

<sup>69</sup> *Id.* at 108.

<sup>70</sup> *Rhea*, 171 N.W. at 107 (Birdzell, J., concurring).

<sup>71</sup> *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.”<sup>72</sup> The dissent cited to *Jacobson*’s cautionary language.

### 3. Later Interpretation of *Jacobson*

By 1934, courts read *Jacobson* to validate preventive smallpox mandates.<sup>73</sup> 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.”<sup>74</sup> A 1934 Texas case decided that it could not evaluate whether an emergency existed.<sup>75</sup> 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.”<sup>76</sup> That court flatly rejected the idea that the court could assess emergency.<sup>77</sup>

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.”<sup>78</sup> The Court read *Jacobson* to justify all vaccination mandates, disregarding its language to reject unreasonable, arbitrary or oppressive state actions.<sup>79</sup>

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.<sup>80</sup> The court even suggested that the plaintiffs lodge objections with the Board of Health rather than the court.<sup>81</sup>

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.<sup>82</sup> 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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<sup>72</sup> *Id.* at 214 (Key, C.J., dissenting).

<sup>73</sup> *Hartman v. May*, 151 So. 737 (Miss. 1934).

<sup>74</sup> *Id.* at 739.

<sup>75</sup> *Booth v. Bd. of Educ.*, 70 S.W.2d 350 (Tex. Civ. App. 1934).

<sup>76</sup> *Id.* at 353.

<sup>77</sup> *Id.*

<sup>78</sup> *Sadlock v. Bd. of Educ.*, 58 A.2d 218, 220 (N.J. 1948).

<sup>79</sup> *Id.*

<sup>80</sup> *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951).

<sup>81</sup> *Id.*

<sup>82</sup> *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.”<sup>83</sup> 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.”<sup>84</sup> 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.”<sup>85</sup>

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.<sup>86</sup> 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.<sup>87</sup> Cases before courts have considered whether membership in an unrecognized faith justifies religious exemption;<sup>88</sup> whether exclusion of unvaccinated children from school following a measles outbreak is justified;<sup>89</sup> whether a parent’s religious objections to vaccination are sincerely held;<sup>90</sup> whether religious exemptions violate the First Amendment establishment clause;<sup>91</sup> and whether state law with no religious exemption violates the First, Fifth and Fourteenth Amendments.<sup>92</sup>

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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<sup>83</sup> *Id.* at 819.

<sup>84</sup> *Jacobson*, *supra* note 9.

<sup>85</sup> *Jacobson*, *supra* note 9.

<sup>86</sup> 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.

<sup>87</sup> 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/SchoolImmunizationExemptionLaws/tabid/14376/Default.aspx>; Hodge & Gostin, *supra* note 29, at 44, n.233.

<sup>88</sup> *Brown v. Stone*, 378 So.2d 218 (Miss. 1979).

<sup>89</sup> *Maricopa County Health Dept. v. Harmon*, 750 P.2d 1364 (Az. Ct. App. 1987).

<sup>90</sup> *LePage v. State*, 18 P.3d 1177 (Wyo. 2001).

<sup>91</sup> *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (E.D. Ark. 2002); *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002).

<sup>92</sup> *Workman v. Mingo County Schs.*, 667 F. Supp. 2d 679 (S.D.W.Va. 2009).

when they refuse to vaccinate their children.<sup>93</sup> Courts have mandated child removal and forced vaccination of children in families who have asserted religious objections.<sup>94</sup>

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.<sup>95</sup> 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."<sup>96</sup>

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."<sup>97</sup> In their view,

Public health programs that are based on force are a relic of the 19<sup>th</sup> century; 21<sup>st</sup> 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 21<sup>st</sup> century requires preserving respect for personal liberty.<sup>98</sup>

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<sup>93</sup> *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).

<sup>94</sup> *Cude*, 377 S.W.2d at 821.

<sup>95</sup> 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).

<sup>96</sup> *Id.*, Gostin, at 580.

<sup>97</sup> Mariner *et. al.*, *supra* note 95, at 586.

<sup>98</sup> *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.”<sup>99</sup> 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.<sup>100</sup> 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<sup>101</sup> and that all non-medical exemptions should be contingent on state discretion.<sup>102</sup> 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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<sup>99</sup> Colgrove & Bayer, *supra* note 95, at 575.

<sup>100</sup> 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.”).

<sup>101</sup> 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.”).

<sup>102</sup> 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.<sup>103</sup>

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.<sup>104</sup>

In the 1960's, mandates served more of a public education role more than a legal one.<sup>105</sup> 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.<sup>106</sup> The federal government established an infrastructure for a war on infectious disease. In 1964, the Advisory Committee on Immunization Practices (ACIP) first met.<sup>107</sup> This organization, under the Public Health Service Act,<sup>108</sup> 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.”<sup>109</sup>

ACIP’s charter requires it to advise about vaccines against vaccine-preventable diseases for use by the public.<sup>110</sup> For children, the charter requires ACIP to create a list of vaccines for federal subsidy.<sup>111</sup> ACIP became the only federal entity to make vaccination recommendations

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<sup>103</sup> 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.”).

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* ([T]he laws served as a ‘means of bringing to individuals’ attention to the continuing publicly perceived need for immunization.”)

<sup>106</sup> 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.”)

<sup>107</sup> CDC: Vaccines Timeline: Fifty Years of Vaccine Progress (Oct. 19, 2006), <http://www.cdc.gov/vaccines/pubs/vacc-timeline.htm>.

<sup>108</sup> 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>.

<sup>109</sup> *Id.* at Objective and Scope of Activities.

<sup>110</sup> *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”)

<sup>111</sup> *Id.*

to the states for public health, and for children in particular.<sup>112</sup> States today rely on ACIP's recommendations for school vaccination mandates. The federal government subsidizes vaccines on the ACIP-recommended list for indigent children,<sup>113</sup> and manufacturers receive liability protection for ACIP-recommended vaccines under the 1986 Law.<sup>114</sup>

ACIP meets several times each year and consists of fifteen non-governmental expert advisors whom the HHS Secretary appoints.<sup>115</sup> 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.<sup>116</sup> Under its charter, ACIP must have at least one citizen representative -- all the rest may be from public health and medical specialties.<sup>117</sup> 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."<sup>118</sup> 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.<sup>119</sup> 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.<sup>120</sup>

## 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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<sup>112</sup> *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...")

<sup>113</sup> *Id.*

<sup>114</sup> 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).

<sup>115</sup> 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.

<sup>116</sup> ACIP Charter, *supra* note 108, at Membership, Subcommittees, and Recordkeeping.

<sup>117</sup> *Id.*

<sup>118</sup> *Jacobson*, 197 U.S. at 29.

<sup>119</sup> ACIP Charter, *supra* note 108, at Authority, Objective, and Description: Objective and Scope of Activities.

<sup>120</sup> 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.<sup>121</sup> 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.<sup>122</sup> The *Reyes* Court rejected the argument that the manufacturer had no duty to warn.<sup>123</sup>

By the 1980's, 250 damage claims against manufacturers for vaccine injury were filed each year.<sup>124</sup> Some vaccine manufacturers left the marketplace and others threatened to do so because of tort liability.<sup>125</sup> Vaccine manufacturers raised the price of vaccines, passing on to consumers the costs of litigation.<sup>126</sup>

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.<sup>127</sup> 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.<sup>128</sup> Later, the American Academy of Pediatrics developed detailed proposals for a compensation scheme that would also relieve doctors of tort liability.<sup>129</sup> And indeed, other developed countries had already adopted governmental compensation schemes for vaccine injury compensation in the 1970's and 1980's.<sup>130</sup>

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."<sup>131</sup> 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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<sup>121</sup> *Davis v. Wyeth*, 399 F.2d 121 (9th Cir. 1968).

<sup>122</sup> *Reyes v. Wyeth*, 498 F.2d 1264 (5th Cir. 1974).

<sup>123</sup> *Id.* at 1293; see COLGROVE, *supra* note 106, at 189.

<sup>124</sup> COLGROVE, *supra* note 106, at 212.

<sup>125</sup> *Id.* at 190, 213.

<sup>126</sup> *Id.* at 212.

<sup>127</sup> *Id.* at 192.

<sup>128</sup> *Id.* at 193.

<sup>129</sup> *Id.* at 208.

<sup>130</sup> *Id.* at 193.

<sup>131</sup> 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.<sup>132</sup>

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.<sup>133</sup>

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.<sup>134</sup> 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.<sup>135</sup> The program was suspended in 1976 and widely viewed as a failure.<sup>136</sup>

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.<sup>137</sup> 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.”<sup>138</sup> 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.<sup>139</sup> This group advocated that the national advisory council on vaccination should have a majority or substantial representation of lay citizens.<sup>140</sup>

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.<sup>141</sup> In *Allison v. Merck*, a mother took

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<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> COLGROVE, *supra* note 106, at 194.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.* at 194-95.

<sup>137</sup> *Id.* at 195-96.

<sup>138</sup> *Id.* at 196.

<sup>139</sup> *Id.*

<sup>140</sup> *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.”)

<sup>141</sup> *Allison v. Merck*, 878 P.2d 948 (Nev. 1994).

her seventeen-month old child to receive a measles, mumps and rubella vaccine.<sup>142</sup> The child contracted encephalitis from the vaccine, leading to blindness, deafness, mental retardation and seizures.<sup>143</sup> The Supreme Court of Nevada recognized the mother's right to bring strict liability and failure to warn claims before a jury.<sup>144</sup>

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.<sup>145</sup> "It is the voluntary choice...that eliminates tort liability," not the "unavoidably unsafe" nature of the product.<sup>146</sup>

The Court pointed out that the mother of the vaccine-injured child "never had any real choice" about vaccinating her son.<sup>147</sup>

[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.<sup>148</sup>

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.<sup>149</sup> 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)"<sup>150</sup> -- did not state that the vaccine could lead to blindness, deafness and mental retardation, as the manufacturer and the government knew were possible.<sup>151</sup> 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.<sup>152</sup>

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<sup>142</sup> *Id.* at 951.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 952.

<sup>145</sup> *Id.* at 954.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* at 957.

<sup>150</sup> *Id.* (internal quotations omitted).

<sup>151</sup> *Id.* at 958.

<sup>152</sup> *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.<sup>153</sup> 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;<sup>154</sup> (2) to insulate industry and the medical profession from liability;<sup>155</sup> (3) to establish a program to compensate the injured;<sup>156</sup> and (4) to promote safer vaccines.<sup>157</sup>

The Law outlined an ambitious agenda of research, production, procurement, distribution, promotion and purchase of vaccines.<sup>158</sup> It established the National Vaccine Injury Compensation Program (VICP) for "vaccine-related injury or death."<sup>159</sup> In its legislative history, Congress made clear that compensation was to be swift, generous and non-adversarial.<sup>160</sup> Congress enacted the statute to compensate children who were injured while serving the public good.<sup>161</sup>

The Program requires the parents of vaccine-injured children to file first in the VICP before in any other court.<sup>162</sup> The Court of Federal Claims in Washington, D.C. administers it.<sup>163</sup> 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.<sup>164</sup> Congress intended to create an administrative program, where families would establish injuries specified in the Vaccine Injury Table and receive compensation.<sup>165</sup>

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<sup>153</sup> See, e.g., *Mazur v. Merck*, 964 F.2d 1348 (3rd Cir. 1992) (affirming summary judgment in favor of appellee drug manufacturer).

<sup>154</sup> 42 U.S.C. § 300aa-2.

<sup>155</sup> *Id.* § 300aa-11.

<sup>156</sup> *Id.* § 300aa-10.

<sup>157</sup> *Id.* § 300aa-27.

<sup>158</sup> *Id.* § 300aa-2.

<sup>159</sup> *Id.* § 300aa-10.

<sup>160</sup> 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.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* § 300aa-11.

<sup>163</sup> *Id.* § 300aa-12.

<sup>164</sup> *Id.* § 300aa-21.

<sup>165</sup> *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.<sup>166</sup> 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.<sup>167</sup> 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.<sup>168</sup> For injuries that were not listed on the Table, however, petitioners would have to prove them based on a preponderance of the evidence.<sup>169</sup>

The VICP requires that petitioners sue HHS; petitioners cannot sue manufacturers or healthcare practitioners in the Program.<sup>170</sup> 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.<sup>171</sup> 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.<sup>172</sup>

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.<sup>173</sup> The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.<sup>174</sup> 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.”<sup>175</sup>

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.<sup>176</sup> 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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<sup>166</sup> *Id.* § 300aa-14.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.* § 300aa-13(a)(1).

<sup>170</sup> *Id.* § 300aa-11(a).

<sup>171</sup> *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.”).

<sup>172</sup> Human Resources Services Commission: National Vaccine Injury Compensation Program, Vaccine Injury Compensation Trust Fund, [http://www.hrsa.gov/vaccinecompensation/VIC\\_Trust\\_Fund.htm](http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm) (“The Trust Fund is funded by a \$.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine).”).

<sup>173</sup> 42 U.S.C. § 300aa-11.

<sup>174</sup> 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](http://www.uscfc.uscourts.gov/sites/default/files/Vaccinerules_20100111_v4.pdf).

<sup>175</sup> 42 U.S.C. § 300aa-10.

<sup>176</sup> *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.<sup>177</sup>

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.”<sup>178</sup> 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.<sup>179</sup> 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.”<sup>180</sup> 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.<sup>181</sup> 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.<sup>182</sup> 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.<sup>183</sup> 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.<sup>184</sup> 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.<sup>185</sup>

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<sup>177</sup> *Id.*

<sup>178</sup> *Id.* § 300aa-16.

<sup>179</sup> *Id.* § 300aa-22.

<sup>180</sup> *Id.* § 300aa-22(b)(1).

<sup>181</sup> *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

<sup>182</sup> *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3rd Cir. 2009), *cert. granted*, 130 S. Ct. 1734 (2010).

<sup>183</sup> *Id.* § 300aa-22(c).

<sup>184</sup> *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....”)

<sup>185</sup> *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."<sup>186</sup> It states that these materials should outline the benefits and risks of vaccines and the availability of the VICP.<sup>187</sup> 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.<sup>188</sup> These provisions establish that trials must be held in three stages: liability, general damages and punitive damages.<sup>189</sup> Punitive damages may be awarded only in the event of fraud or other criminal or illegal activity relating to the vaccine safety and effectiveness.<sup>190</sup>

Furthering vaccine safety and surveillance, the Law requires certain recordkeeping by healthcare providers and industry.<sup>191</sup> 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.<sup>192</sup> 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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<sup>186</sup> *Id.* § 300aa-26.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* § 300aa-21.

<sup>189</sup> *Id.* § 300aa-23.

<sup>190</sup> *Id.* § 300aa-23(d).

<sup>191</sup> *Id.* § 300aa-25; *Id.* § 300aa-28.

<sup>192</sup> *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.<sup>193</sup>

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."<sup>194</sup> 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.<sup>195</sup> 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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<sup>193</sup> 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>.

<sup>194</sup> 42 U.S.C. § 300aa-1.

<sup>195</sup> 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.<sup>196</sup> 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.<sup>197</sup> 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.<sup>198</sup> 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."<sup>199</sup> Dr. Healy has been sharply critical of a medical community unwilling to investigate the tens of

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<sup>196</sup> 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](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](http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_7-18yrs-schedule-pr.pdf) (last visited Sep. 4, 2010).

<sup>197</sup> 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](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.")

<sup>198</sup> Lou Cooper *et al.*, *Protecting Public Trust in Immunization*, 122 PEDIATRICS 149, 152 (2008) at 151.

<sup>199</sup> Interview with Dr. Healy at [http://www.cbsnews.com/stories/2008/05/12/cbsnews\\_investigates/main4086809.shtml](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.<sup>200</sup>

## 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;<sup>201</sup> adverse reactions in clinical trials may be found to be coincidental;<sup>202</sup> safety tests may be designed to achieve desired results rather than actual assessments;<sup>203</sup> and vaccines may not have been evaluated for "carcinogenic, mutagenic potential or impairment of fertility."<sup>204</sup>

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.<sup>205</sup> 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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<sup>200</sup> *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?")

<sup>201</sup> *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](http://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf).

<sup>202</sup> *See, e.g.*, Sanofi Pasteur Poliovirus Vaccine Inactivated IPOL, <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf> ("Although no causal relationship has been established, deaths have occurred in temporal association after...IPV.").

<sup>203</sup> *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](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf); *see also* Blaxill, *infra* note 251.

<sup>204</sup> *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](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").

<sup>205</sup> *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](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].”<sup>206</sup>

## 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.<sup>207</sup> Simian Virus 40, inadvertently contained in intramuscular polio vaccines, has been associated with several different human cancers, including mesotheliomas and brain cancers.<sup>208</sup>

Certain vaccine ingredients used as preservatives and adjuvants, such as aluminum and mercury, are recognized neurotoxins.<sup>209</sup> 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.<sup>210</sup> 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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<sup>206</sup> 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)).

<sup>207</sup> 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>.

<sup>208</sup> 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).

<sup>209</sup> 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>.

<sup>210</sup> 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/BloodVaccines/SafetyAvailability/VaccineSafety/UCM096228>.

effects for at least 50 years and that the vaccine manufacturers did not conduct necessary toxicology studies to establish safety.<sup>211</sup>

### **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.<sup>212</sup>

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.<sup>213</sup> 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.<sup>214</sup> 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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<sup>211</sup> George Lucier, "Thimerosal is a Developmental Neurotoxicant," report available at <http://www.vtce.org/mercury/lucier.pdf>.

<sup>212</sup> 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>.

<sup>213</sup> Vaccine Rules of U.S. Fed. Cl., Fed. Cl. R. app. 8(b)(1), *supra* note 174.

<sup>214</sup> 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.”<sup>215</sup>

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.”<sup>216</sup> 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.”<sup>217</sup>

According to Dr. Chen’s testimony, in 1995, vaccine safety was .2% of the total vaccine budget of about \$1 billion.<sup>218</sup> 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%.<sup>219</sup>

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.<sup>220</sup> 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.”<sup>221</sup> Failure to report criticism of vaccine safety is unlikely to resolve the serious questions that surround it.

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<sup>215</sup> *Id.* at 262.

<sup>216</sup> *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).

<sup>217</sup> *Id.* at 270, n. 142.

<sup>218</sup> *Id.*

<sup>219</sup> Cooper *et al.*, *supra* note 198.

<sup>220</sup> 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).

<sup>221</sup> *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.<sup>222</sup> 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.<sup>223</sup> HHS also redefined “encephalopathy,” a recognized compensable injury, to exclude almost all cases from on-Table compensation.<sup>224</sup> 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.<sup>225</sup> 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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<sup>222</sup> 60 Fed. Reg. 7678 (Feb. 8, 1995).

<sup>223</sup> 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).

<sup>224</sup> “Proposed Changes to the Vaccine Injury Table,” HHS memo dated Aug. 21, 1992, at <http://www.hhs.gov/news/press/pre1995pres/920821.txt>.

<sup>225</sup> *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.”<sup>226</sup>

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.<sup>227</sup>

The former Chief Special Master, Gary Golkiewicz, acknowledged the Program’s bias against petitioners.<sup>228</sup> 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.<sup>229</sup>

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.”<sup>230</sup> 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.<sup>231</sup> But more than 4 out of 5 claimants have not received compensation.<sup>232</sup> 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.<sup>233</sup> The total

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<sup>226</sup> Fisher, *supra* note 212.

<sup>227</sup> Vaccine Injury Table, *supra* note 165.

<sup>228</sup> ARTHUR ALLEN, VACCINE: THE CONTROVERSIAL STORY OF MEDICINE’S GREATEST LIFESAVER 293 (2007).

<sup>229</sup> *Id.*

<sup>230</sup> 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>.

<sup>231</sup> National Vaccine Injury Compensation Program, *supra* note 4.

<sup>232</sup> *Id.*

<sup>233</sup> 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](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.<sup>234</sup> 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.”<sup>235</sup> Both industry and the medical community lobbied for this lowered information standard after *Reyes v. Wyeth*.<sup>236</sup>

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.<sup>237</sup> The initial versions were 12 pages long and required parental signature. But pediatricians found the brochures were “scaring” parents and took too much time.<sup>238</sup> The American Academy of

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<sup>234</sup> 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.”).

<sup>235</sup> 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.”).

<sup>236</sup> *Reyes v. Wyeth*, *supra* notes 122 to 130 and accompanying text.

<sup>237</sup> See Severyn, *supra* note 206, at 270 (citing 42 U.S.C. § 300aa-26(c) (1986)).

<sup>238</sup> *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."<sup>239</sup>

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.<sup>240</sup>

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.<sup>241</sup> 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.<sup>242</sup> 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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<sup>239</sup> *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)).

<sup>240</sup> Measles, Mumps, & Rubella (MMR) Vaccines: What You Need To Know (Mar. 13, 2008), <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-mmr.pdf>.

<sup>241</sup> 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).

<sup>242</sup> 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.<sup>243</sup> 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.<sup>244</sup> Merck voluntarily withdrew Rotashield from the market thirteen months after launch due to serious adverse reactions.<sup>245</sup> 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.<sup>246</sup>

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,<sup>247</sup> prompting criminal investigation of some.<sup>248</sup>

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<sup>243</sup> 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.”).

<sup>244</sup> *Id.* at 8.

<sup>245</sup> *Id.* at 9.

<sup>246</sup> *Id.* at 2.

<sup>247</sup> DEPT’ 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).

<sup>248</sup> *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.<sup>249</sup> During her tenure at CDC, ACIP approved Merck's Gardasil vaccine for human papilloma virus against cervical cancer.<sup>250</sup> 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.<sup>251</sup>

While conflicts of interest in vaccine mandates were identified as a problem at least as early as 1911,<sup>252</sup> 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.<sup>253</sup> Also in 2002, the pharmaceutical industry employed 675 full-time lobbyists in Washington, more than the number of people in both Houses of Congress.<sup>254</sup> It spent \$91 million annually for lobbying.<sup>255</sup> 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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<sup>249</sup> Dr. Julie Gerberding Named President of Merck Vaccines (Dec. 21, 2009), [https://merck.com/newsroom/news-release-archive/corporate/2009\\_1221.html](https://merck.com/newsroom/news-release-archive/corporate/2009_1221.html).

<sup>250</sup> *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>.

<sup>251</sup> 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).

<sup>252</sup> *See supra* notes 66 to 70, discussing *Rhea v. Bd. of Educ.*

<sup>253</sup> MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES* 11 (2005).

<sup>254</sup> *Id.* at 198.

<sup>255</sup> *Id.*

groups,<sup>256</sup> such as the Immunization Action Coalition,<sup>257</sup> 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.<sup>258</sup> These companies manufacture almost 80 percent of the global vaccine market as well.<sup>259</sup> 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.<sup>260</sup> 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,<sup>261</sup> it now has high margins and is expanding with double digit growth.<sup>262</sup> 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.<sup>263</sup> 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.<sup>264</sup> 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 the 1986 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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<sup>256</sup> *Id.* at 138.

<sup>257</sup> IAC Funding, Immunization Action Coalition, <http://www.immunize.org/aboutus/funding.asp> (listing seven drug companies that donated money in 2010).

<sup>258</sup> The Vaccine Industry – An Overview (July 2010), [http://www.vaccineethics.org/issue\\_briefs/industry.php](http://www.vaccineethics.org/issue_briefs/industry.php).

<sup>259</sup> *Id.*

<sup>260</sup> *Id.*

<sup>261</sup> *Id.*

<sup>262</sup> See Salinsky & Werble, *supra* note 197, at 12.

<sup>263</sup> 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>.

<sup>264</sup> *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.<sup>265</sup> 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.<sup>266</sup> 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.”<sup>267</sup> Pfizer, through its recent purchase of Wyeth, makes one vaccine among ACIP-recommended vaccines.<sup>268</sup>

Merck voluntarily withdrew its anti-inflammatory drug Vioxx from the market in 2004.<sup>269</sup> 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.<sup>270</sup> The Congressional hearings suggested that Merck knew of the likelihood of these side effects in 1998, before the FDA approved the drug in 1999.<sup>271</sup> The approval process suggested conflicts of interest.<sup>272</sup> To compensate victims, Merck entered into a settlement to pay \$4.85 billion to nearly 50,000 eligible claimants.<sup>273</sup> Merck manufactures ten vaccines that are among ACIP-recommended vaccines.<sup>274</sup>

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<sup>265</sup> 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](http://www.businesswire.com/portal/site/home/permalink/ndmViewId=news_view&newsId=20090902005690&newsLang=en). (last visited Sept. 4, 2010).

<sup>266</sup> *See Pfizer to Pay Record \$2.3 Billion Penalty*, ASSOCIATED PRESS (Sep. 2, 2009), <http://www.msnbc.msn.com/id/32657347/>.

<sup>267</sup> *Id.*

<sup>268</sup> 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).

<sup>269</sup> Merck News Release: Merck Announces Voluntary Worldwide Withdrawal of Vioxx, Sep. 30, 2004, [https://merck.com/newsroom/vioxx/pdf/vioxx\\_press\\_release\\_final.pdf](https://merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf).

<sup>270</sup> 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](http://www.pbs.org/newshour/bb/health/july-dec04/vioxx_11-18.html).

<sup>271</sup> *Id.*

<sup>272</sup> 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).

<sup>273</sup> 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.”).

<sup>274</sup> 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.<sup>275</sup> 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.”<sup>276</sup> 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.”<sup>277</sup> Glaxo manufactures nine ACIP-recommended vaccines.<sup>278</sup>

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.<sup>279</sup> 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.<sup>280</sup> 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 Lilly corporation blanket immunity from any side effects that may have resulted from thimerosal’s past use in childhood vaccines.<sup>281</sup>

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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<sup>275</sup> 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>.

<sup>276</sup> 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>.

<sup>277</sup> *Id.*

<sup>278</sup> 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).

<sup>279</sup> 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.

<sup>280</sup> 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.”

<sup>281</sup> 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*<sup>282</sup> and HHS Secretary's Sebelius' discouragement of press inquiries into vaccine safety.<sup>283</sup> 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;<sup>284</sup> 9% have attention deficit hyperactivity disorder;<sup>285</sup> 8% have a learning disability;<sup>286</sup> 2% have an allergic condition;<sup>287</sup> and 1% has an autism spectrum disorder,<sup>288</sup> 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 28<sup>th</sup> among world nations for infant mortality, the death rate before one year of age, behind almost all other developed nations.<sup>289</sup>

There are plausible links between vaccines and these troubling health statistics.<sup>290</sup> Petitions in the Court of Federal Claims for vaccine injury show that many individuals think their health problems are vaccine-related.<sup>291</sup> It is scientifically plausible that childhood vaccines may play a role in children's health problems today.

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<sup>282</sup> 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](http://www.abanet.org/publiced/preview/briefs/pdfs/09-10/09-152_RespondentAmCuUSA.pdf).

<sup>283</sup> See Allen interview with HHS Secretary Sebelius, *supra* note 220.

<sup>284</sup> Summary Health Statistics for U.S. Children: National Health Interview Survey, 2009, [http://www.cdc.gov/nchs/data/series/sr\\_10/sr10\\_247.pdf](http://www.cdc.gov/nchs/data/series/sr_10/sr10_247.pdf), asthma data at 25.

<sup>285</sup> *Id.* at 27, ADHD data.

<sup>286</sup> *Id.* at 27, learning disability data.

<sup>287</sup> *Id.* at 26, allergy data.

<sup>288</sup> CDC Data and Statistics, Autism Spectrum Disorders, at <http://www.cdc.gov/ncbddd/autism/data.html>.

<sup>289</sup> CIA World Factbook at <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html>.

<sup>290</sup> 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.

<sup>291</sup> 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.<sup>292</sup> 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."<sup>293</sup> 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.<sup>294</sup> 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.<sup>295</sup>

Several childhood vaccines in state mandates today, such as vaccines against hepatitis B, human papilloma virus (HPV) and tetanus,<sup>296</sup> are not rationally related to school attendance. Hepatitis B is transmissible through intravenous needle exchange or sexual contact; HPV is

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<sup>292</sup> *Wong Wai*, 103 F. at 10.

<sup>293</sup> *Mariner et al*, *supra* note 95, at 588.

<sup>294</sup> 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](http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_0-6yrs-schedule-pr.pdf).

<sup>295</sup> 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>.

<sup>296</sup> 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),<sup>297</sup> or the disease is not contagious (tetanus),<sup>298</sup> or the illness does not pose fatal risks or imminent harm to the individual or society (varicella and seasonal influenza).<sup>299</sup> 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 14<sup>th</sup> 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.<sup>300</sup> 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*.<sup>301</sup>

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<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

<sup>299</sup> 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>.

<sup>300</sup> *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.").

<sup>301</sup> *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.<sup>302</sup> 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.<sup>303</sup> Some countries, such as Japan, have no compulsory vaccination laws and achieve high rates of vaccine uptake through persuasion alone.<sup>304</sup> 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.<sup>305</sup>

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).

<sup>302</sup> 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.

<sup>303</sup> 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](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>.

<sup>304</sup> *Id.*, *Childhood Immunisation* at 5.

<sup>305</sup> 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'](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'](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.<sup>306</sup> 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.

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<sup>306</sup> See Brief of Vaccine Injured Petitioners Bar Association, *supra* note 160, at 7.