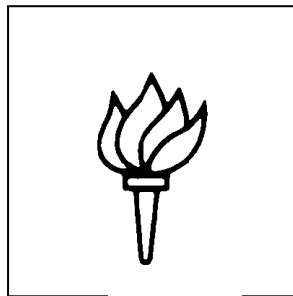


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Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children

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INTRODUCTION

The federal government today recommends that all children between birth and age eighteen years receive seventy doses of sixteen vaccines.¹ Of these recommended vaccines, the majority of states mandate between thirty and forty-five vaccine doses for children to be able to attend school.² Forty-seven states require preschool-age children to receive three doses of the hepatitis B vaccine to attend public school.³ The federal government recommends that infants receive their first dose of the hepatitis B vaccine shortly after birth, while they are in the hospital.⁴

The disease hepatitis B today affects approximately 730,000 people in the United States.⁵ Hepatitis B is usually a chronic disease for which there is no known cure; it can lead to severe liver disease and death.⁶ People spread the disease through intimate contact, primarily through sex and shared intravenous drug use.⁷ The vaccine has demonstrated efficacy in checking the spread of the disease among the at risk population.⁸

So what is the medical rationale for the hepatitis B vaccination mandate for

1. *Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States, 2011*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/0-6yrs-schedule-bw.pdf> (last visited Nov. 9, 2011); *Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States, 2011*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/7-18yrs-schedule-pr.pdf> (last visited Nov. 28, 2011).

2. See *Hepatitis B Prevention Mandates for Daycare and K-12*, IMMUNIZATION ACTION COALITION, <http://www.immunize.org/laws> (last updated May 26, 2011) (showing vaccination mandates by state). While the Coalition is solely responsible for the website, its information is based on government sources, and the website is funded in part by the Centers for Disease Control and Prevention.

3. *Id.* (showing that only Alabama, Montana, and South Dakota have no hepatitis B mandates for daycare or school).

4. Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I: Immunization of Infants, Children and Adolescents*, 54 MORBIDITY & MORTALITY WKLY. REP., Dec. 23, 2005, at 1, 15, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>.

5. Annemarie Wasley et al., *The Prevalence of Hepatitis B Virus Infection in the United States in the Era of Vaccination*, 202 J. INFECTIOUS DISEASES 192 (2010).

6. *Hepatitis B Information for the Public*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/B> (last updated Mar. 12, 2009).

7. Ctrs. for Disease Control & Prevention, *supra* note 4.

8. Ctrs. for Disease Control & Prevention, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 MORBIDITY & MORTALITY WKLY. REP., Nov. 22, 1991, at 1, 2, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>.

very young children? What legal requirements must a state meet to enable it to impose such a mandate? To what extent have the legal requirements for vaccination mandates changed over time? Do states today meet the constitutional requirements for the hepatitis B vaccination mandate for very young children? These are the questions that this Article explores.

The Article highlights the historical requirements for vaccination mandates: necessity, reasonable means, proportionality, non-discrimination, harm avoidance, and fairness. It considers Fourteenth Amendment Due Process and Equal Protection Clause requirements. It shows that the vaccination mandate that the Supreme Court upheld in 1905 was markedly different from today's hepatitis B mandate for preschoolers.⁹ The *Jacobson* decision upheld a mandate for the entire population, in the context of an airborne epidemic emergency, with a relatively small monetary fine for non-compliance. Today's hepatitis B mandate is imposed exclusively on children, for preventive purposes, although children are at minimal risk of contracting the disease—a disease that is transmitted exclusively through intimate contact—on penalty of limiting the right to an education.

The Article is divided into three Parts. Part I reviews public health law related to vaccination, including *Jacobson v. Massachusetts*; the public health mechanism to recommend vaccination mandates; and the Congressional statute that created the federal vaccine program. Part II considers more recent Supreme Court precedent on personal autonomy, addressing rights in bodily integrity and medical decision-making. Part III considers a hypothetical challenge to New York State's hepatitis B vaccination mandate for preschool children. Part III also considers the evolution of federal hepatitis B recommendations, financial considerations in mandates, vaccine safety, informed consent, and the manner in which the Supreme Court might review a challenge. The Article concludes that the constitutionality of state vaccination mandates against hepatitis B disease for preschool children is questionable.

I. PUBLIC HEALTH LAW

A. *Judicial Decisions Before Jacobson v. Massachusetts*

Infectious diseases were leading causes of death in the United States until the 20th century. During the 19th century, movement from the countryside to cities, with overcrowded housing, inadequate sanitation and impure drinking water, spurred outbreaks of infectious disease.¹⁰ These conditions resulted in repeated epidemics of cholera, typhoid, influenza, and malaria. In 1900, more

9. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

10. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Control of Infectious Diseases*, 48 MORBIDITY & MORTALITY WKLY. REP. 621, 622 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm>.

than thirty percent of all deaths occurred among children under five years of age.¹¹ Although vaccination carried recognized 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.¹² In the 19th 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.¹³ Compulsory smallpox vaccination was introduced in some jurisdictions in the 1800s to ensure “herd immunity.” When a large proportion of a community is vaccinated, these individuals form a barrier which prevents spread of the disease to those not vaccinated and those for whom the vaccine is ineffective. The proportion required for “herd immunity” varies depending on the infectious agent. For polio, the proportion is about eighty percent; for measles, it is above ninety percent.¹⁴

Vaccination mandates are laws requiring individuals to be vaccinated or face penalties, such as a fine or deprivation of the right to attend 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, or have, laws that force vaccination on unwilling subjects. In other words, no states physically restrain and vaccinate individuals, although this practice reportedly has occurred.¹⁵

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 to protect the public health during an epidemic.¹⁶ In 1900, the Utah Supreme Court

11. *Id.* at 621.

12. *Jacobson*, 197 U.S. at 34 (“Smallpox is known of all to be a dangerous and contagious disease.” (quoting *Viemeister v. White*, 72 N.E 97, 99 (N.Y. 1903))).

13. *Id.*

14. LAW IN PUBLIC HEALTH PRACTICE 340 (Richard A. Goodman et al. eds., 2003); see also Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 419-21 (2004) (describing herd immunity); Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 388 (2008) (describing the theory of herd immunity, which postulates that, as vaccination rates rise, chains of communicable disease transmission are interrupted and diseases—and the risks they present to the public health—can be eliminated altogether).

15. 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.”).

16. *Duffield v. Williamsport Sch. Dist.*, 29 A. 742 (Pa. 1894).

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.¹⁷ 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.”¹⁸ In 1900, a California court established that no vaccination mandate could be applied in a racially discriminatory manner because it would violate the equal protection clause of the Fourteenth Amendment to the Constitution.¹⁹

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.²⁰ 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.²¹

While judicial decisions preceding *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 a single vaccine against one disease.

B. Jacobson v. Massachusetts

Today there are school vaccination laws in fifty states²² and mandates for certain categories of adults, such as military personnel²³ and healthcare

17. *State ex rel. Cox v. Bd. of Educ.*, 60 P. 1013, 1020 (Utah 1900).

18. *Freeman v. Zimmerman*, 90 N.W. 783, 784 (Minn. 1902).

19. *Wong Wai v. Williamson*, 103 F. 1 (N.D. Cal. 1900).

20. *Viemeister v. White*, 84 N.Y.S. 712, 713 (App. Div. 1903).

21. *Id.* at 718.

22. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 833 (2002) (“Each state has school vaccination laws which require children of appropriate age to be vaccinated for several communicable diseases.”).

23. Military regulations require U.S. soldiers to be vaccinated against a number of diseases, including hepatitis A, influenza, tetanus, diphtheria, measles, mumps, rubella, polio, and yellow

workers.²⁴ There are also public health acts for emergencies with vaccination provisions in many states.²⁵ In 1905, the Supreme Court in *Jacobson* decided that states may impose reasonable regulations to ensure the public health and safety, even if such regulations infringe individuals' personal liberty.

Jacobson came to the United States 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 five-dollar fine (the equivalent of about \$110 today).²⁶ Mr. Jacobson refused to comply with the regulation and would agree neither to be vaccinated nor pay the five-dollar fine. Mr. Jacobson argued that the regulation violated his rights under the Fifth and Fourteenth Amendments.²⁷ 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 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. States retain the right to issue reasonable regulations, it argued, and, in the context of a potential smallpox epidemic, Cambridge's ordinance was not "unreasonable, arbitrary and oppressive."²⁸ It was the legitimate province of the elected legislature to decide what measures would be best, and the legislature was unquestionably aware of opposing views about vaccination among the medical profession and the

fever. See PETER J. SCHOOMAKER ET AL., ARMY REGULATION 40-562, IMMUNIZATIONS AND CHEMOPROPHYLAXIS (2006), available at http://www.vaccines.mil/documents/969r40_562.pdf.

24. 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 & PREVENTION, <http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/default.asp> (last modified Sept. 19, 2011). For instance, in New York, hospital employees must be offered hepatitis B vaccine and are required to be vaccinated against measles, mumps, and rubella. *Vaccines & Immunizations: Immunization Administration Requirements for State: NY*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/Administration.asp?statetmp=NY> (last modified Sept. 19, 2011).

25. See JAMES G. HODGE, JR. & LAWRENCE O. GOSTIN, THE MODEL STATE EMERGENCY HEALTH POWERS ACT - A BRIEF COMMENTARY (2002), available at <http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf>.

26. 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 \$114.59 in 2011. *CPI Inflation Calculator*, BUREAU LABOR STAT., http://www.bls.gov/data/inflation_calculator.htm (last visited Nov. 9, 2011).

27. See U.S. CONST. amend. XIV, § 1 ("No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state 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.").

28. *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905).

electorate. The regulation required the inhabitants to be vaccinated only when “that was necessary for the public health or the public safety.”²⁹ The regulation did not violate the Fourteenth Amendment because it was “applicable equally to all in like condition.”³⁰ 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.³¹

Jacobson’s claims arose under the Fourteenth Amendment’s Due Process and Equal Protection clauses, but the decision makes no mention of substantive due process under the Fourteenth Amendment. Only two months later, the Court articulated that doctrine in the *Lochner* decision.³² Lawrence Gostin, a public health law authority, cited *Jacobson* for the proposition that public health regulations require five elements to be constitutional: (1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness.³³ In trying to square *Jacobson* with *Lochner*, a recent commentator, Dr. Allan Jacobs, argued that “[t]he Court’s proscription of ‘arbitrary and oppressive’ state action may be invoking procedural due process in banning ‘arbitrary’ action, and substantive due process in proscribing ‘oppressive’ action.”³⁴

However, the Court did not give states blind deference. It justified the Cambridge regulation as reasonable, recognizing that it imposed one vaccine, on the entire adult population, in the context of a contagious, deadly epidemic, with a relatively small fine for non-compliance. The regulation excluded some children from compliance. The Court’s paradigm was clear: a mandate is permissible in “an emergency,”³⁵ when there was “imminent danger,”³⁶ when “an epidemic of disease . . . threatens the safety of [society’s] members,”³⁷ when there was “the pressure of great dangers,”³⁸ and for an “epidemic that imperiled an entire population.”³⁹ The Court’s language—emergency, imminent danger, peril to the entire population—suggests grave risk. While Professor Shapiro in his response downplays this high threshold, I believe Justice Harlan’s words speak for themselves.

Describing the potential abuse of police power, the Court opined:

29. *Id.* at 27.

30. *Id.* at 30.

31. *Id.* at 29-30.

32. *Lochner v. New York*, 198 U.S. 45 (1905) (striking down a state public health regulation as a restriction on the substantive due process right to freedom of contract).

33. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 126-28 (2d ed. 2008).

34. Allan J. Jacobs, *Needles and Notebooks: The Limits of Requiring Immunization for School Attendance*, 33 *HAMLINE L. REV.* 171, 183 (2010) (discussing *Jacobson v. Massachusetts*).

35. *Jacobson*, 197 U.S. at 27.

36. *Id.* at 29.

37. *Id.* at 27.

38. *Id.* at 29.

39. *Id.* at 31.

[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.⁴⁰

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.”⁴¹ It stated:

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.⁴²

The Court cautioned that if a state statute purported to be 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 courts to so adjudge.”⁴³ The Court anticipated that the police power to vaccinate might include circumstances when regulations could be “so arbitrary and oppressive . . . as to justify the interference of the courts to prevent wrong and oppression.”⁴⁴

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.⁴⁵ Because of *Jacobson*, medical exemptions exist in all fifty states.⁴⁶ Although the *Jacobson* decision did not create them, statutory religious exemptions exist in forty-eight states today,⁴⁷ and philosophical or conscientious belief exemptions exist by statute in twenty states.⁴⁸

40. *Id.* at 28 (citing *Wis., Minn. & Pac. R.R. v. Jacobson*, 179 U.S. 287 (1900)).

41. *Id.*

42. *Id.* at 29.

43. *Id.* at 31.

44. *Id.* at 38.

45. *Id.* at 39.

46. Hodge & Gostin, *supra* note 22, 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 the judicial and ethical principles of harm avoidance asserted by the Supreme Court in *Jacobson v. Massachusetts*.”).

47. See *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NAT’L CONF. ST. LEGISLATURES (Mar. 2011), <http://www.ncsl.org/default.aspx?tabid=14376> (only West Virginia and Mississippi do not have religious exemptions).

48. *Id.* Under a philosophical exemption, a person need not specify the basis for her objection to vaccination.

Although the Court was clearly wary of treading on 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.”⁴⁹ It made clear that no law should be interpreted in practice to be “cruel and inhuman in the last degree.”⁵⁰

1. *Constitutional Standards of Review*

It is not certain what standard of review the Supreme Court would apply to a state compulsory vaccination mandate today. The Supreme Court decided *Jacobson* before it had adopted explicit standards for review of government authority. In *Jacobson*, the Court required only that Massachusetts’s statute be rationally related to the purpose of eradicating infectious disease. Since the 1940s, however, as Part II explores, the Court has held that a higher standard must apply if a state law impinges on a fundamental liberty interest.⁵¹ For a law to be constitutional under a strict scrutiny test, the highest standard, there must be a compelling governmental interest and the law must be narrowly tailored to achieve its end.⁵² In cases where strict scrutiny does not apply, the Supreme Court usually uses the lowest standard, the rational basis test. The rational basis test applies when the rights at stake are not considered fundamental. Under this standard of review, “if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the [law] so long as it bears a rational relation to some legitimate end.”⁵³

Between these two extremes of strict scrutiny and rational basis review, the Supreme Court has required an intermediate level of scrutiny or a “pumped-up” rational basis test for liberty interests after *Jacobson*.⁵⁴ In these cases, the Supreme Court has struck down questionable state laws on the grounds that the state interest did not outweigh an individual’s liberty interest. Several prominent public health scholars have suggested that a case like *Jacobson* today would require intermediate scrutiny because of the clear liberty interests at stake.⁵⁵

In recent decisions, the Supreme Court has itself read *Jacobson* to support the inference that the Constitution protects a patient’s liberty interest in the right

49. *Jacobson*, 197 U.S. at 39.

50. *Id.*

51. *See infra* Part II.

52. *Id.*

53. *Romer v. Evans*, 517 U.S. 620, 631 (1996).

54. *City of Cleburne Texas v. Cleburne Living Center*, 473 U.S. 432 (1985).

55. GOSTIN, *supra* note 33, at 141 (“The Court has found a constitutionally protected liberty interest in bodily integrity, but it has yet to hold that such an interest is ‘fundamental.’”); KENNETH R. WING & BENJAMIN GILBERT, *THE LAW AND THE PUBLIC’S HEALTH* 24 (7th ed. 2007) (“[I]f *Lochner* or *Jacobson* were argued today, the analysis in both cases would likely adopt the ‘rational basis/close scrutiny’ rhetoric that modern courts have developed in the last several decades . . .”).

to refuse care, suggesting that it would apply intermediate scrutiny.⁵⁶ The Court has found that “[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.”⁵⁷

2. Jacobson’s *Early Legacy*

Initial interpretation of *Jacobson* was circumspect. From 1907 to 1914, state appellate and supreme courts construed *Jacobson* as permitting single vaccination mandates during smallpox outbreaks.⁵⁸ The courts upheld mandates and exclusion of unvaccinated school children during emergencies. These decisions applied an “oppressive or arbitrary” standard and looked for evidence of public necessity, and, particularly, the threat of epidemic.⁵⁹ These decisions held that statutes must incorporate medical exemptions.⁶⁰ The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.⁶¹

Beginning in 1916, however, judicial interpretations of *Jacobson* broadened. The Alabama Supreme Court read *Jacobson* to contain 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.⁶² 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 for children, and not adults, were valid because a group of children “constitutes 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.”⁶³ The court deferred to municipal authorities on public health.⁶⁴

The Kentucky Supreme Court reached a similar conclusion that same year, 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.”⁶⁵ These decisions interpreted *Jacobson* expansively; in neither situation was there an

56. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990).

57. *Washington v. Harper*, 494 U.S. 210, 229 (1990).

58. *Hammond v. Town of Hyde Park*, 80 N.E. 650 (Mass. 1907); *State ex rel. O’Bannon v. Cole*, 119 S.W. 424 (Mo. 1909); *People v. Ekerold*, 105 N.E. 670 (N.Y. 1914); *McSween v. Bd. of Sch. Trs.*, 129 S.W. 206 (Tex. Civ. App. 1910); *State ex rel. McFadden v. Shorrock*, 104 P. 214 (Wash. 1909).

59. *O’Bannon*, 119 S.W. at 427.

60. *McFadden*, 104 P. at 216.

61. *Hammond*, 80 N.E. at 651.

62. *Herbert v. Demopolis Sch. Bd. of Educ.*, 73 So. 321 (Ala. 1916).

63. *Id.* at 323.

64. *Id.*

65. *Bd. of Trs. v. McMurtry*, 184 S.W. 390, 394 (Ky. 1916).

imminent danger or necessity for the state to act in self-defense.

3. *Zucht v. King*: Jacobson's Legacy for School Children

All states today compel elementary education, whether in public or private schools or at home. States compel education under the police power and under the state's role as *parens patriae*, or protector of the state. The Supreme Court's decision in *Wisconsin v. Yoder* acknowledged that compulsory "education is necessary to prepare citizens to participate effectively and intelligently in our open political system."⁶⁶ Since 1943, the Supreme Court has recognized that "the state as *parens patriae* may restrict the parent's control by requiring school attendance."⁶⁷

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.⁶⁸ In a cursory, unanimous decision, the Court cited *Jacobson* as settling that compulsory vaccination may be a requirement of public school admission.⁶⁹ Denying the petitioner's claim of infringement of her Fifth and Fourteenth Amendment rights based on *Jacobson*,⁷⁰ the Court did consider that the law might have been administered in a way that violated her rights.⁷¹ 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."⁷² It did not inquire into the circumstances of the epidemic and affirmed substantial deference to the school board, with smallpox as the relevant, but unnamed, backdrop.

Zucht did not alter *Jacobson*'s analysis that necessity is required to justify state police powers, but it applied this analysis outside of a mandate for the whole population. Whether the Justices thought that *Jacobson*'s analysis was sufficient or that 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.

Zucht did shift *Jacobson*'s paradigm, though, by upholding a mandate exclusively for children, a subpopulation, and by affirming the validity of a preventive mandate for a disease not in circulation. It is notable that the Cambridge regulation in *Jacobson* specifically excluded some children as excessively vulnerable subjects for compulsory vaccination with the smallpox

66. *Wisconsin v. Yoder*, 406 U.S. 205, 221 (1972).

67. *Prince v. Massachusetts*, 321 U.S. 158, 166 (1943).

68. *Zucht v. King*, 260 U.S. 174, 176 (1922).

69. *Id.* at 176.

70. *Id.*

71. *Id.* at 177.

72. *Id.*

vaccine.⁷³ *Zucht* did not acknowledge that there might be an equal protection problem if the mandate was imposed selectively on children rather than the population as a whole.⁷⁴ Still, *Zucht* did not lessen *Jacobson*'s requirements to compel vaccination.⁷⁵

Zucht implicitly acknowledged that school attendance creates unique threats to the health of the children gathered there. Hundreds, or even thousands, of children may be in one building for several hours a day, making transmission of airborne disease likely. As Dr. Allan Jacobs noted:

A public health necessity exists when the disease is serious and vaccination to obtain herd immunity is substantially safer than failure to vaccinate. The reasonable means test is satisfied by the nexus between school attendance and disease transmission. The proportionality test is satisfied by the relative safety of the vaccine. Finally, the principle of harm avoidance is met by allowing exemption for medical conditions that make vaccination detrimental to a child's health.⁷⁶

Jacobson requires that decisions to mandate vaccination for school attendance be subject to a balancing test that assesses the severity of the disease, the risks of the vaccine, the amount of overall clinical experience with the vaccine, and alternative methods of prevention. As Dr. Jacobs suggested, "The absence of linkage of a disease to school activities should weigh heavily against a vaccination requirement."⁷⁷

Some commentators reject the view that there must be a close nexus between school and vaccination to warrant a state mandate.⁷⁸ Indeed, states do impose vaccines on school children for tetanus, a noncontagious disease, and for relatively mild childhood illnesses, such as rubella, largely to protect pregnant mothers from infection. One expert sees such mandates as instrumental in furthering "society's strong interest in ensuring that people are protected from

73. *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905) ("[T]here are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years.").

74. *Id.*

75. *Zucht* raises some procedural problems in interpretation. The writ of error was dismissed because of the lack of a federal question. Justice Brandeis noted at the end of the opinion that some of the issues the case raised would only be appropriate before the Court on a writ of *certiorari*, not a writ of error. This may help to explain why this critically important decision on childhood vaccination is so cursory.

76. Jacobs, *supra* note 34, at 192-93.

77. *Id.* at 193.

78. Scholars favoring the human papilloma virus vaccine mandate hold this view. See, e.g., Cynthia Dailard, *Achieving Universal Vaccination Against Cervical Cancer in the United States: The Need and the Means*, 9 GUTTMACHER POL'Y REV. 12 (2006); Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731 (2008).

disease throughout their lives.”⁷⁹ Others suggest that vaccination mandates can realistically only be for children because “no national program exists to support vaccine purchase and infrastructure for vaccine delivery to uninsured and underinsured adults.”⁸⁰ As a matter of constitutional law, unresolved questions remain about which criteria are essential for valid vaccination mandates.

By 1934, courts read *Jacobson* to validate preventive smallpox mandates.⁸¹ 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.”⁸² A 1934 Texas court decided that it could not evaluate whether an emergency existed.⁸³ It explained, “[W]e cannot attempt to measure how pressing a necessity must be in order to allow the board’s discretion to be exercised.”⁸⁴ That court flatly rejected the idea that the court could assess emergency.⁸⁵

Courts increasingly deferred to states’ police powers in the ensuing years. In 1948, the New Jersey Supreme Court, upholding a school 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.”⁸⁶ The Court seemed to read *Jacobson* to justify all vaccination mandates, disregarding its language to reject unreasonable, arbitrary or oppressive state actions.⁸⁷

A 1951 Arkansas case asked the court to evaluate the validity of a preventive school vaccination mandate, but that court decided that it was not its place to judge the efficacy or safety of vaccinations.⁸⁸ The court even suggested that the plaintiffs should lodge objections with the Board of Health rather than the court.⁸⁹

By the mid-1950s, it was arguably settled law that school vaccination mandates were presumptively valid. *Jacobson*’s cautionary language had not figured meaningfully into the case’s application. In 1964, the Arkansas Supreme

79. Dailard, *supra* note 78, at 14.

80. Eric E. Mast et al., Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults*, 55 MORBIDITY & MORTALITY WKLY. REP., Dec. 8, 2006, at 1, 13 (“In contrast to vaccination of children, no national program exists to support vaccine purchase and infrastructure for vaccine delivery to uninsured and underinsured adults.”).

81. *Hartman v. May*, 151 So. 737 (Miss. 1934).

82. *Id.* at 739.

83. *Booth v. Bd. of Educ.*, 70 S.W.2d 350 (Tex. Civ. App. 1934).

84. *Id.* at 353.

85. *Id.*

86. *Sadlock v. Bd. of Educ.*, 58 A.2d 218, 220 (N.J. 1948).

87. *Id.*

88. *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951).

89. *Id.*

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.⁹⁰ 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 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."⁹¹ The Arkansas Supreme Court upheld the prosecutor's charge of child neglect against the father who refused to vaccinate his children on religious grounds.

Given such extreme deference to police powers for many decades, potential plaintiffs did not challenge *Jacobson* directly. Potential plaintiffs opposing vaccination mandates presumably considered direct challenges futile. Instead, since the 1960s, 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.⁹² Cases before courts have considered whether membership in an unrecognized faith justifies religious exemption;⁹³ whether exclusion of unvaccinated children from school following a measles outbreak is justified;⁹⁴ whether a parent's religious objections to vaccination are sincerely held;⁹⁵ whether religious exemptions violate the First Amendment establishment clause;⁹⁶ and whether state laws with no religious exemption violate the First, Fifth, and Fourteenth Amendments.⁹⁷ As the Arkansas case above illustrates, states sometimes punish non-compliant parents harshly. Even when religious exemptions exist, courts sometimes find parents liable for child neglect when they refuse to vaccinate their children.⁹⁸ Courts have mandated child removal and forced vaccination in families that have asserted religious objections.⁹⁹

Courts have used *Jacobson* to justify results that the original decision did not condone: vaccination mandates exclusively for children with no imminent disease outbreaks and with serious penalties for noncompliance. Punishments include loss of education, social isolation, parents' loss of custodial rights, child-

90. *Cude v. State*, 377 S.W.2d 816 (Ark. 1964).

91. *Id.* at 819.

92. See Hodge & Gostin, *supra* note 22, at 874 n.233; *States With Religious and Philosophical Exemptions from School Immunization Requirements*, *supra* note 47.

93. *Brown v. Stone*, 378 So.2d 218 (Miss. 1979).

94. *Maricopa Cnty, Health Dep't v. Harmon*, 750 P.2d 1364 (Ariz. Ct. App. 1987).

95. *LePage v. State (In re LePage)*, 18 P.3d 1177 (Wyo. 2001).

96. *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002); *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (E.D. Ark. 2002).

97. *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348 (4th Cir. 2011); *Workman v. Mingo Cnty. Schs.*, 667 F. Supp. 2d 679 (S.D. W. Va. 2009).

98. *In re Christine M.*, 595 N.Y.S.2d 606 (Fam. Ct. 1992); *In re Elwell*, 284 N.Y.S.2d 924 (Fam. Ct. 1967).

99. *Cude v. State*, 377 S.W.2d 816, 821 (Ark. 1964).

neglect sanctions against parents, and, even, forced vaccination. In *Jacobson* and *Zucht*, the Supreme Court upheld mandates for one vaccine during airborne epidemics. Courts have expanded the original *Jacobson* precedent dramatically.

4. *The Advisory Committee on Immunization Practices (ACIP)*

Although *Jacobson* today remains the landmark case on state compulsory vaccination, the federal government began to assume the driving role in immunization policy in the 1960s. Government experts within the Centers for Disease Control and Prevention (CDC) adopted the goal of eradicating infectious disease, establishing an infrastructure for a war against it. In 1964, the Advisory Committee on Immunization Practices (ACIP) met for the first time.¹⁰⁰ This organization, under the Public Health Service Act, was 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.”¹⁰¹ ACIP remains the key decision-making body within the federal government on childhood immunization policy.

ACIP’s charter requires it to advise the public about vaccines against vaccine-preventable diseases. For children, the charter requires ACIP to create a list of vaccines for federal subsidy. ACIP became the only federal entity to make vaccination recommendations to the states for public health, and for children in particular.¹⁰² States today rely on ACIP’s recommendations for school vaccination mandates. The federal government subsidizes vaccines on the ACIP-recommended list for indigent children, and manufacturers receive liability protection for ACIP-recommended vaccines by statute.¹⁰³

ACIP meets several times each year and consists of fifteen non-governmental expert advisers whom the Secretary of the Department of Health and Human Services (HHS) appoints.¹⁰⁴ 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

100. *Vaccines Timeline: 50 Years of Vaccine Progress*, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 19, 2006), <http://www.cdc.gov/vaccines/pubs/vacc-timeline.htm>.

101. See 42 U.S.C. § 217a (2006) (“The Secretary may . . . appoint such advisory councils or committees . . . for the purpose of advising him in connection with any of his functions.”); *ACIP Charter: Authority, Objective, and Description, Authority*, CENTERS FOR DISEASE CONTROL & PREVENTION (Apr. 6, 2010), <http://www.cdc.gov/vaccines/recs/acip/download/charter.pdf>.

102. *ACIP Charter: Authority, Objective, and Description, Authority*, *supra* note 101 (ACIP is tasked to “establish . . . and revise a list of vaccines for administration to children and adolescents . . . along with schedules . . .”).

103. See 42 U.S.C. § 300aa-6 (2006) (authorizing appropriations necessary to carry out the statute’s provisions); see also 42 U.S.C. § 300aa-11 (providing liability protection for manufacturers of vaccines).

104. *ACIP Charter: Authority, Objective, and Description, Authority*, *supra* note 101.

representatives of liaison organizations. Under its charter, ACIP must have at least one consumer or community representative—all the rest may be from public health and medical specialties.¹⁰⁵ In other words, of the forty-nine people charged to deliberate on national vaccine policy, only one must represent the public.

From ACIP's inception, *Jacobson's* requirements and the federal government's mission for immunization pointed 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. By contrast, ACIP, the new driver of national immunization policy, aimed to prevent and control infectious disease and to fund state childhood vaccination programs. ACIP's mission does not reference *Jacobson's* requirements of self-defense, imminent danger, necessity, or local authorities' discretion. Instead, the federal government created in ACIP an infrastructure to prevent and control communicable diseases particularly among children through compulsory vaccination. In 1965, one year after its inception, ACIP urged the creation of a federal program to compensate victims of vaccine injury and to relieve manufacturers of ordinary tort liability.¹⁰⁶ ACIP recommended that this would keep the vaccine market stable, keep vaccines affordable, and ensure compensation to victims. Manufacturers and medical communities joined this recommendation.¹⁰⁷ Later, the American Academy of Pediatrics developed detailed proposals for a compensation scheme that would also relieve doctors of tort liability.¹⁰⁸ Indeed, other developed countries had already adopted governmental compensation schemes for vaccine injury in the 1970s and 1980s.¹⁰⁹ In 1986, the United States Congress would adopt such a program.

5. *The National Childhood Vaccine Injury Act of 1986 (NCVIA)*

Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA) almost two decades after the ACIP first recommended a government compensation scheme.¹¹⁰ In the intervening two decades, vaccine injury litigation had become more commonplace, more costly and, therefore, more problematic to manufacturers and doctors who administered vaccines. Manufacturers threatened to leave the marketplace unless the federal government granted them tort liability protection. Seeking to shield the relatively new childhood immunization program, Congress held hearings, including testimony from the pharmaceutical

105. *Id.*

106. JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 192 (2006).

107. *Id.* at 193.

108. *Id.* at 208.

109. *Id.* at 193.

110. Pub. L. No. 99-660, 100 Stat. 3755.

industry, doctors, and parents of vaccine-injured children. Through the NCVIA, Congress sought to (1) create the infrastructure for a national immunization program,¹¹¹ (2) insulate industry and the medical profession from liability,¹¹² (3) establish a program to compensate the injured,¹¹³ and (4) promote safer vaccines.¹¹⁴

The NCVIA outlined an ambitious agenda of research, production, procurement, distribution, promotion and purchase of vaccines.¹¹⁵ It established the National Vaccine Injury Compensation Program (VICP) for “vaccine-related injury or death.”¹¹⁶ In its legislative history, Congress made clear that compensation was to be swift, generous, and nonadversarial.¹¹⁷ Congress enacted the statute to compensate children who were injured while serving the public good.¹¹⁸

The Program requires the parents of vaccine-injured children to file first in the VICP before they may file a lawsuit in any ordinary civil court.¹¹⁹ In other words, the Program has original jurisdiction over all claims of childhood vaccine injury from federally recommended vaccines. The Court of Federal Claims in Washington, D.C. administers it.¹²⁰ 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.¹²¹ Congress intended to create an administrative program, where families would establish injuries specified in the Vaccine Injury Table and receive compensation.¹²²

When Congress passed the NCVIA, there were many recognized vaccine injuries, including anaphylaxis, encephalopathy, paralytic polio, and other acute complications, including death.¹²³ Almost all injuries on the Vaccine Injury Table were to have occurred within thirty days of vaccination; most were to have occurred within hours or a couple days of the vaccination.¹²⁴ If petitioners met the precise requirements of the specified injuries, then they would have a presumption of compensation.¹²⁵ For injuries that were not listed on the Table,

111. 42 U.S.C. § 300aa-2 (2006).

112. *Id.* § 300aa-11.

113. *Id.* § 300aa-10.

114. *Id.* § 300aa-27.

115. *Id.* § 300aa-2.

116. *Id.* § 300aa-10.

117. H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344.

118. *Id.*

119. *See* 42 U.S.C. §§ 300aa-2, -11(a)(2)(A).

120. *Id.* § 300aa-12.

121. *Id.* § 300aa-21.

122. *Id.* § 300aa-14; *see Vaccine Injury Table*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/vaccinecompensation/vaccinetable.html> (last visited Dec. 3, 2011).

123. 42 U.S.C. § 300aa-14.

124. *Id.*

125. *Id.*

however, petitioners would have to prove them based on a preponderance of the evidence.¹²⁶

The VICP requires that petitioners sue HHS; petitioners may not sue manufacturers or healthcare practitioners in the Program.¹²⁷ 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.¹²⁸ The source of VICP compensation is the Vaccine Injury Trust Fund, a fund now containing more than \$3.3 billion from an excise tax of seventy-five cents on the sale of every vaccine.¹²⁹

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.¹³⁰ The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.¹³¹ 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.”¹³²

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.¹³³ These caps have not changed since 1986. The Act also provides for “reasonable attorney’s fees and costs” for bringing a petition so that petitioners do not have to pay lawyers out of pocket or out of the proceeds of a judgment, as they would have to do in civil court under a contingency fee arrangement.¹³⁴

The NCVIA 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.”¹³⁵ This three-year statute of limitations is

126. *Id.* § 300aa-13(a)(1).

127. *Id.* § 300aa-11(a).

128. *See, e.g.,* Calandrillo, *supra* note 14, 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.” (footnote omitted)).

129. *National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/vaccinecompensation/index.html> (last visited Nov. 9, 2011) (“The Trust Fund is funded by a \$0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine).”).

130. 42 U.S.C. § 300aa-11 (giving jurisdiction to the court of federal claims).

131. 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.”).

132. 42 U.S.C. § 300aa-10.

133. *Id.* § 300aa-15.

134. *Id.*

135. *Id.* § 300aa-16.

considerably shorter than most state tort statutes for injury to minors.

In perhaps the most significant part of the statute, the NCVIA restricts vaccine manufacturers' liability for those vaccines included on ACIP's recommended childhood schedule. Under its 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."¹³⁶

In the 1990s, the number of cases of alleged vaccine injury filed with the VICP jumped dramatically. Many families alleged that their children's autism resulted from certain vaccine antigens or from a mercury-containing vaccine preservative, thimerosal, used in multi-dose vaccine vials.¹³⁷ Thimerosal is approximately fifty percent mercury by weight.¹³⁸ Some of these families successfully litigated in civil court, bypassing the VICP, arguing that the use of thimerosal in infant vaccines was a defective design and outside VICP jurisdiction.¹³⁹

In 2008, the Georgia Supreme Court held that civil courts must decide design defect claims on a case-by-case basis.¹⁴⁰ By contrast, in 2009, the Third Circuit Court of Appeals held that all vaccine injuries allegedly due to design defects of approved vaccines are by definition unavoidable under the NCVIA.¹⁴¹ In 2011, the U.S. Supreme Court decided *Bruesewitz v. Wyeth*, a case interpreting the VICP's jurisdiction and resolving the split in interpretation between the Supreme Court of Georgia and the Third Circuit Court of Appeals. The Court addressed whether the NCVIA preempts all vaccine design defect lawsuits. In a 6-2 decision, the Supreme Court upheld the Third Circuit's decision to disallow all design defect claims.¹⁴² These claims are thus barred in all courts, as the VICP hears cases of individual injury only and is not equipped to hear design defect claims.

In addition to broad liability protection, the NCVIA provides another important protection to manufacturers.¹⁴³ It provides that vaccine manufacturers are not liable for damages if they fail to give direct warnings to patients.¹⁴⁴

136. *Id.* § 300aa-22(b)(1).

137. *Autism Decisions and Background*, U.S. CT. FED. CLAIMS, <http://www.uscfc.uscourts.gov/node/5026> (last visited Oct. 17, 2011).

138. *Thimerosal in Vaccines, Thimerosal as a Preservative*, U.S. FOOD & DRUG ADMIN., available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm> (last updated Mar. 31, 2010).

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

140. *Id.*

141. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *aff'd*, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011).

142. *Bruesewitz*, 131 S. Ct. 1068.

143. 42 U.S.C. § 300aa-22(c).

144. *Id.* (explaining that there is no liability "solely due to the manufacturer's failure to

Resting on the “learned intermediary” doctrine, which states that it is sufficient to inform doctors of the risks, manufacturers bear no obligation to provide accurate or complete information to those actually vaccinated.¹⁴⁵

Complementing manufacturers’ relief from disclosure requirements, another provision exempts doctors from substantial federal disclosure requirements. It tasks the HHS Secretary to “develop and disseminate vaccine information materials.”¹⁴⁶ It states that these materials should outline the benefits and risks of vaccines and the availability of the VICP.¹⁴⁷ Doctors are obliged to provide families with these information materials, but there is no penalty for failing to do so.

Jacobson, *Zucht*, the ACIP, and the NCVIA all continue to play critical roles in U.S. vaccine law and policy.

II. THE SUPREME COURT’S PERSONAL AUTONOMY JURISPRUDENCE

Since *Jacobson*, the Supreme Court has decided several cases about medical intervention, bodily integrity, and sexual autonomy, further articulating what constitutes valid individual liberty interests and the level of scrutiny a court must apply to laws restricting them. These personal autonomy cases contrast starkly with *Jacobson*’s legacy. While none of the cases addressing personal autonomy touch on vaccination, they are relevant to how the Supreme Court would view a challenge under the Fourteenth Amendment to a compulsory vaccination mandate today.

A. Forced Sterilization, Contraception and Abortion

The first case where the Supreme Court invoked the term “strict scrutiny” was *Skinner v. Oklahoma*, a 1942 case that struck down a state criminal statute on forced sterilization.¹⁴⁸ Having only fifteen years earlier upheld forced sterilization of a woman in a state mental institution in *Buck v. Bell*,¹⁴⁹ the Supreme Court rejected the Oklahoma statute on Fourteenth Amendment Equal Protection grounds. In *Buck v. Bell*, the Court had relied on *Jacobson* to justify the state’s exercise of the police power;¹⁵⁰ in *Skinner*, the Court imposed a heightened standard of review and found the state’s statute lacking.¹⁵¹

The Court noted that “[m]arriage and procreation are fundamental to the

provide direct warnings to the injured party of the potential dangers resulting from the administration of the vaccine”).

145. *Id.*

146. *Id.* § 300aa-26.

147. *Id.*

148. *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

149. *Buck v. Bell*, 274 U.S. 200 (1927).

150. *Id.* at 204.

151. *Skinner*, 316 U.S. at 541.

very existence and survival of the race. The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects.”¹⁵² The Court noted that the individual would be “forever deprived of a basic liberty” and “that strict scrutiny of the classification which a State makes in a sterilization law is essential, lest unwittingly or otherwise invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws.”¹⁵³ The Court found that the criminal statute was being applied unequally, forcing sterilization on those convicted of theft but not on those convicted of embezzlement—crimes which carried the same penalty.¹⁵⁴ Justice Jackson, in his concurrence, raised due process issues as well as those of equal protection.¹⁵⁵ The case suggests that when “fundamental civil rights” or “basic liberties” are at stake, the Court must use strict scrutiny.

Although *Buck v. Bell* has never been formally overruled, the Colorado Supreme Court summarized the contemporary view that “since *Skinner*, commentators generally have concluded that compulsory sterilization laws, no matter what their rationale, are unconstitutional in the absence of evidence that compulsory sterilization is the only remedy available to further a compelling governmental interest.”¹⁵⁶

In the 1960s and 1970s, the Court began to recognize liberty interests in contraception and abortion decision-making. In 1961, the Court upheld a state statute prohibiting access to contraception in *Poe v. Ullman*. Justice Harlan in dissent outlined the balancing tests for “fundamental liberties” in the face of state police powers.¹⁵⁷ His reasoning strongly influenced the Court’s later decision in *Griswold v. Connecticut*, which required the state to show that the contraceptive restriction was “necessary, and not merely rationally related to, the accomplishment of a permissible state policy.”¹⁵⁸

Harlan’s *Poe* dissent reasoned that due process guarantees are the “bulwarks . . . against arbitrary legislation” that cannot be reduced to a simple formula.¹⁵⁹ He suggested that the balance between liberty and the demands of organized society must be “a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, and which also recognizes . . . that certain interests require particularly careful

152. *Id.*

153. *Id.*

154. *Id.* at 541-42.

155. *Id.* at 546-47 (Jackson, J., concurring).

156. *In re A.W.*, 637 P.2d 366, 368-69 (Colo. 1981).

157. *Poe v. Ullman*, 367 U.S. 497, 523-55 (1961) (Harlan, J., dissenting).

158. *Griswold v. Connecticut*, 381 U.S. 479, 497 (1965) (citing *McLaughlin v. Florida*, 379 U.S. 184 (1964)).

159. *Poe*, 367 U.S. at 541 (Harlan, J., dissenting) (citing *Hurtado v. California*, 110 U.S. 516, 532 (1884)).

scrutiny of the state needs asserted to justify their abridgement.”¹⁶⁰ Justice Harlan asserted that, when one is reviewing something that is a “basic liberty,” such as the ability to procreate, there are limits to what the government may impose. Justice Harlan argued that the contraception statute at issue should be subjected to “strict scrutiny.”¹⁶¹

Although the right to personal autonomy in sexual conduct was highlighted in *Griswold*, the decision also concerned the right to protect one’s health through autonomous medical decisions without government interference. The movement for birth control was in part to address the toll on women’s health from pregnancy.¹⁶² The lack of a medical exception in the statute motivated the petitioners as well as liberty interests.

The Court in 1973 applied strict scrutiny to the right to an abortion during the first trimester. *Roe v. Wade* declared that “the right to personal privacy includes the abortion decision, but that this right is not unqualified.”¹⁶³ The Court found that a woman’s right to abort outweighed the state’s compelling interest in protection of fetal life in the first trimester of pregnancy. Justice Rehnquist dissented, arguing that the appropriate standard of review should be rational basis and that the right to abortion was not deeply rooted in the country’s history.¹⁶⁴

B. The Right to Make Medical Treatment Decisions

In the 1990s, the Court decided three cases on the limits of medical autonomy: *Cruzan v. Missouri*, *Washington v. Harper*, and *Glucksberg v. Washington*. While the Court did not adopt a strict scrutiny standard of review in any of them, the majority did adopt intermediate scrutiny. These decisions recognized individuals’ strong liberty interests in the right to make decisions about bodily integrity and medical treatment.

In 1990, the Court directly addressed the right of an individual to refuse unwanted medical intervention. In *Washington v. Harper*, the Court recognized a prisoner’s “significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment.”¹⁶⁵ The Court reversed the Supreme Court of Washington’s application of a strict scrutiny standard and decided “whether the regulation is reasonably related to legitimate penological interests.”¹⁶⁶ It upheld the right of the state to administer the drugs according to the procedures in the statute, but

160. *Id.* at 543 (citations omitted).

161. *Id.* at 548.

162. B. Jessie Hill, *The Constitutional Right To Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 307 (2007).

163. *Roe v. Wade*, 410 U.S. 113, 154 (1973).

164. *See id.* at 173-76.

165. *Washington v. Harper*, 494 U.S. 210, 221 (1990).

166. *Id.* at 223 (internal quotation mark omitted).

acknowledged that forcible medical intervention was “a substantial interference with that person’s liberty,” including the possibility of “serious, even fatal, side effects.”¹⁶⁷ The Court nonetheless upheld the statute as permissible largely based on the security interest in the prison environment and deference to professional medical judgment in the due process procedures.

Justice Stevens, joined by Justices Marshall and Brennan, dissented from the majority about the liberty interest, the standard of review, and the quality of due process available under the statute.¹⁶⁸ The dissent argued that the Court “undervalued [the] respondent’s liberty interest. . . and has concluded that a mock trial before an institutionally biased tribunal constitutes ‘due process of law.’”¹⁶⁹ It states that “a competent individual’s right to refuse such medication is a fundamental liberty interest deserving the highest order of protection.”¹⁷⁰ It does not agree that the statute takes the inmate’s interests into account, and argues that the policy “sweepingly sacrifices the inmate’s substantive liberty interest to refuse psychotropic drugs, regardless of his medical interests, to institutional and administrative concerns.”¹⁷¹ Justice Stevens argued that the policy was not narrowly drawn, that the decision makers were biased, and that there was an insufficient showing of the state’s necessity to medicate.¹⁷²

The *Cruzan* decision followed just two months later, recognizing a constitutionally protected liberty interest in refusing unwanted medical treatment for an incapacitated individual in a coma. The Court upheld a state statute that required that the evidence of the individual’s wishes in such circumstances be “clear and convincing.”¹⁷³ The Court noted the deep legal roots of the right to refuse medical treatment. It noted that “[a]t common law, even the touching of one person by another without consent and without legal justification was a battery.”¹⁷⁴ It quoted a Supreme Court decision from 1891 stating, “No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”¹⁷⁵

Citing Justice Cardozo, the *Cruzan* majority wrote, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”¹⁷⁶ The Court noted that “[t]he informed consent doctrine has become

167. *Id.* at 229.

168. *Id.* at 237 (Stevens, J., dissenting).

169. *Id.*

170. *Id.* at 241.

171. *Id.* at 245-46.

172. *Id.* at 242-57.

173. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 280-81 (1990).

174. *Id.* at 269.

175. *Union Pac. R.R. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

176. *Cruzan*, 497 U.S. at 269 (quoting *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93

firmly entrenched in American tort law.”¹⁷⁷ It found that the Court’s prior decisions, including *Jacobson*, implied the constitutionally protected liberty interest in refusing unwanted medical treatment.¹⁷⁸

Justice O’Connor’s concurrence was more emphatic about the liberty interest to refuse unwanted medical treatment. She wrote, “[T]he liberty guaranteed by the Due Process Clause must protect, if it protects anything, an individual’s deeply personal decision to reject medical treatment, including the artificial delivery of food and water.”¹⁷⁹ She argued that “notions of liberty are inextricably entwined with our idea of physical freedom and self-determination” and that “the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.”¹⁸⁰

Justice Scalia’s concurrence emphasized that the best way to address such issues was through the Equal Protection Clause: “Our salvation is the Equal Protection Clause, which requires the democratic majority to accept for themselves and their loved ones what they impose on you and me.”¹⁸¹

As in *Washington v. Harper*, Justices Brennan and Marshall dissented, with Justice Blackmun joining them as well. They argued that Nancy Cruzan had a “fundamental right to be free of unwanted medical care,” that her right was “not outweighed by any interests of the state,” and that “improperly biased procedural obstacles imposed by the Missouri Supreme Court impermissibly burden that right.”¹⁸² The dissenters argued that because the Missouri statute impinged on a fundamental right, the state interest had to be narrowly tailored. Fundamental rights are to be protected even from “subtle governmental interference.”¹⁸³ They criticized the majority for recognizing a “general liberty interest,” but failed to state explicitly what the “measure of that liberty interest or its application” was.¹⁸⁴ If, as Justice O’Connor conceded, a competent person has a right to refuse medical treatment, then it “must be fundamental,” they argued.¹⁸⁵ “[The] freedom from unwanted medical attention is unquestionably among those principles ‘so rooted in the traditions and conscience of our people as to be ranked as fundamental,’” they concluded.¹⁸⁶ While they acknowledged that the individual’s liberty right is not absolute, Missouri’s general interest in protecting life did not outweigh Cruzan’s parents’ petition to end hydration and nutrition.¹⁸⁷

(1914)).

177. *Id.*

178. *Id.* at 278.

179. *Id.* at 289 (O’Connor, J., concurring).

180. *Id.* at 287.

181. *Id.* at 300 (Scalia, J., concurring).

182. *Id.* at 302 (Brennan, J., dissenting).

183. *Id.* at 304.

184. *Id.*

185. *Id.*

186. *Id.* at 305 (quoting *Snyder v. Mass.*, 291 U.S. 97, 105 (1934)).

187. *Id.* at 313.

Justice Stevens wrote a separate, forceful dissent. He characterized the state's interest as an "abstract, undifferentiated interest in the preservation of life," that overwhelms the best interests of Nancy Cruzan.¹⁸⁸ He argued that Cruzan's parents' rights should prevail, and that the state should not substitute its decisions for theirs.¹⁸⁹ He argued that the "sanctity, and individual privacy, of the human body is obviously fundamental to liberty. Every violation of a person's body is an invasion of his or her liberty."¹⁹⁰ He argued that "lives do not exist in abstraction from persons, and to pretend otherwise is not to honor but to desecrate the State's responsibility for protecting life."¹⁹¹ While the majority did not join his view, the Court's range of opinion had shifted towards greater recognition of the liberty interest.

In 1997, the Court decided *Glucksberg v. Washington*, unanimously holding that there was no right to assisted suicide.¹⁹² Nevertheless, the Court reaffirmed its line of cases finding a liberty interest in the Due Process Clause and requiring heightened protection against government interference. The Court reviewed the interests in marriage, procreation, education, contraception, bodily integrity and abortion.¹⁹³ It stated that "we have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment."¹⁹⁴ The Court contrasted its decision in *Cruzan*, holding that the common law had long recognized the right to refuse unwanted medical treatment, with *Glucksberg*, where it found the right to assisted suicide was not deeply rooted.

Justice Stevens in his concurrence wrote that the right to refuse treatment comes not only from the common law, but also from the more fundamental rights to bodily integrity and dignity. He agreed with the Court's conclusion, but would have applied strict scrutiny.¹⁹⁵

C. The Right to Autonomy in Sexual Relations

In 2003, the Court affirmed a heightened standard of review for the liberty interest in an individual's sexual autonomy.¹⁹⁶ In *Lawrence v. Texas*, the Court

188. *Id.* at 331 (Stevens, J., dissenting).

189. *Id.* at 337.

190. *Id.* at 342.

191. *Id.* at 356-57.

192. *Washington v. Glucksberg*, 521 U.S. 702, 705-06 (1997).

193. *Id.* at 719-20 (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992) (abortion); *Loving v. Virginia* 388 U.S. 1 (1967) (marriage); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (marital privacy, contraception); *Rochin v. California*, 342 U.S. 165 (1952) (bodily integrity); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (having children); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (educational choice)).

194. *Id.* at 720.

195. *Id.* at 741-43 (Stevens, J., concurring).

196. *Lawrence v. Texas*, 539 U.S. 558 (2003).

found a Texas statute criminalizing homosexual sodomy unconstitutional. The majority found that individuals enjoy heightened liberty protection from government intrusion in their private dwellings and personal autonomy. The Court overruled its prior decision in *Bowers v. Hardwick*, supporting its reversal with the Court's precedents applying intermediate scrutiny in *Casey v. Planned Parenthood*, an abortion rights case, and in *Romer v. Evans*, a discrimination case on the basis of sexual orientation.¹⁹⁷ The majority argued that Justice Stevens's dissent in *Bowers* should have been the majority decision.¹⁹⁸ By contrast, Justice O'Connor wrote that she found the Texas statute unconstitutional only on equal protection grounds. She cited Justice Jackson on the Equal Protection Clause:

The framers of the Constitution knew, and we should not forget today, that there is no more effective practical guaranty against arbitrary and unreasonable government than to require that the principles of law which officials would impose upon a minority be imposed generally. Conversely, nothing opens the door to arbitrary action so effectively as to allow those officials to pick and choose only a few to whom they will apply legislation and thus to escape the political retribution that might be visited upon them if larger numbers were affected.¹⁹⁹

Justices Scalia, Rehnquist and Thomas dissented, arguing that the majority applied "an unheard-of form of rational-basis review."²⁰⁰ The dissent argued that no fundamental right had been impinged; that there was a rational relationship with a legitimate state interest; and that neither due process nor equal protection of the law were violated.²⁰¹ Justice Thomas added in a separate dissent that while the Texas statute was "uncommonly silly," there was no constitutional basis for protection of the right to personal autonomy.²⁰²

Thus since the 1940s, the Supreme Court has applied intermediate or strict scrutiny to cases about sterilization, abortion, medical treatment, and sexual autonomy. Yet, it has never revisited compulsory vaccination since 1922, and has not treated the issue in any depth since 1905. Based on the review of recent personal autonomy cases, it seems likely that the Supreme Court would apply at least an intermediate level of scrutiny to a state vaccination mandate case, even though *Jacobson* required only a rational basis test.

197. *Id.* at 573-74.

198. *Id.* at 578.

199. *Id.* at 585 (citing *Ry. Express Agency, Inc. v. New York*, 336 U.S. 106, 112-13 (1949)).

200. *Id.* at 586.

201. *Id.* at 605.

202. *Id.* at 605-06.

The Supreme Court today has two distinct and somewhat contradictory lines of cases that relate to vaccination mandates—one focused on public health and the limits of individual liberty and the other focused on the individual's fundamental claims to bodily integrity and autonomy. Both lines of cases have potential life-and-death implications for individuals and society.

The contours of the vaccine issue have changed fundamentally since the early 1900s. Now at issue are thirty to forty-five preventive vaccinations whose administration start on the day of birth and which are compelled almost exclusively on children. It is possible that the Supreme Court may be called on in the foreseeable future to decide a case about the constitutionality of vaccination mandates.

III. A HYPOTHETICAL CHALLENGE TO A HEPATITIS B VACCINATION MANDATE FOR PRESCHOOL CHILDREN

Forty-seven states impose hepatitis B vaccination mandates for daycare and school attendance, or both.²⁰³ New York's public health law on school immunizations is representative, stating that a "school" includes "any public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten,"²⁰⁴ and defining "child" as "any person between the age of two months and eighteen years."²⁰⁵ According to the statute, every child must receive the federally recommended doses of the hepatitis B vaccine, and several other vaccines, for school admission. "No principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school, in excess of fourteen days, without the certificate [of immunizations]."²⁰⁶

The statute provides for the right of medical exemption if the required immunizations "may be detrimental to the child's health."²⁰⁷ And it grants the right to religious exemption to parents who object to their child's immunization due to "genuine and sincere religious beliefs which are contrary to the practices herein required."²⁰⁸ New York State does not afford individuals a philosophical or personal belief exemption to vaccination. It also requires the vaccination of children who do not attend school and have no valid exemptions.²⁰⁹

Are hepatitis B vaccination mandates for preschool aged children under the age of six constitutional under the Fourteenth Amendment Due Process and

203. *Hepatitis B Prevention Mandates for Daycare and K-12*, *supra* note 2 (showing that only Alabama, Montana, and South Dakota have no hepatitis B mandates for daycare or school).

204. N.Y. PUB. HEALTH LAW § 2164(1)(a) (Consol. 2011).

205. *Id.* § 2164(1)(b).

206. *Id.* § 2164(7)(a).

207. *Id.* § 2164(8).

208. *Id.* § 2164(9).

209. *Id.* § 2164(8-a).

Equal Protection Clauses? Consider the hypothetical challenge of parents seeking to place their son in a preschool in New York City that requires compliance with the hepatitis B mandate. Assume that the parents of the three-year-old boy complied with all other vaccination mandates but refused this medical intervention against a disease that poses a negligible risk to their son and his classmates. They also believe that the vaccine itself carries irrational risks without any countervailing necessity.²¹⁰ The child is ineligible for a religious exemption because the family does not oppose the mandate on religious grounds. They oppose the mandate because it is unreasonable, arbitrary, oppressive, and against the child's best interests, concerns that *Jacobson* squarely addressed.

Imagine that they challenged the validity of the New York State regulation under the Fourteenth Amendment Due Process and Equal Protection Clauses. The New York State trial and appellate courts upheld the mandate but the New York Court of Appeals, the state's highest court, reversed and held that the hepatitis B vaccination mandate violated the Fourteenth Amendment Due Process Clause following the Supreme Court's precedents in *Jacobson*, *Harper*, *Cruzan*, and *Glucksberg*. New York State petitioned for *certiorari* and the U.S. Supreme Court granted it.

How might the Supreme Court balance the interests of the state and young child? The Court would have to look to *Jacobson*, *Zucht*, and the Court's most recent precedents on personal autonomy. But before turning to how the Court might decide, the Article reviews background about the disease itself, federal policy recommendations, and hepatitis B vaccination mandates that commenced in the 1990s. The Article will then return to the hypothetical challenge.

A. Hepatitis B Disease, Federal Policy, Vaccination Mandates and Public Response

The CDC provides the following information about hepatitis B disease:

Hepatitis B is a contagious liver disease that results from infection with the hepatitis B virus. It can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Hepatitis B is usually spread when blood, semen, or another body fluid from a person infected with the hepatitis B virus enters the body of someone who is not infected. This can happen through sexual contact with an infected person or sharing needles, syringes, or other drug-injection equipment. Hepatitis B can also be passed from an infected mother to her baby at birth.²¹¹

210. See *infra* notes 211-258 and accompanying text.

211. *Hepatitis B Information for the Public*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/B> (last updated Mar. 12, 2009).

While the ACIP notes that transmission through saliva is possible, it suggests that nonsexual interpersonal contact must occur over an extended period, such as living with a chronic hepatitis B infected person in the same household.²¹² Official CDC and ACIP materials do not suggest that transmission between young children through routine contact poses a significant threat.

1. *The 1982 and 1988 ACIP Recommendations*

In 1982, ACIP recommended the hepatitis B virus (HBV) vaccine only for those people “at substantial risk of HBV infection who are demonstrated or judged likely to be susceptible.”²¹³ ACIP noted that the United States is “an area of low HBV prevalence,” and that “the estimated lifetime risk of HBV . . . [is] approximately 5% for the population as a whole.”²¹⁴ ACIP recommended the vaccine only for “higher risk groups”: health-care workers, infants born to mothers infected with hepatitis B, and people likely to be in sexual or “needle stick” contact with those infected with hepatitis B.²¹⁵ In other words, ACIP recommended the vaccine to healthcare workers, drug addicts, homosexual and heterosexual adults with multiple sexual partners, and infants of infected mothers.

In 1988, ACIP issued another statement about the vaccine, calling for screening of all pregnant women to identify which mothers were infected—it estimated 16,500 mothers per year—and recommended that their infants be vaccinated. Without vaccination, ACIP estimated that 3500 infants would become chronic hepatitis B carriers.²¹⁶ It stated:

Prenatal screening of all pregnant women would identify those who are HBsAg-positive [hepatitis B surface antigen positive] and thus would allow treatment of their newborns with hepatitis B immune globulin (HBIG) and hepatitis B (HB) vaccine, a regimen that is 85%-95% effective in preventing the development of the HBV chronic carrier state.²¹⁷

212. Mast et al., *supra* note 80, at 5.

213. Ctrs. for Disease Control & Prevention, *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, 31 MORBIDITY & MORTALITY WKLY. REP. 317 (1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001116.htm>.

214. *Id.*

215. *Id.*

216. Ctrs. for Disease Control & Prevention, *Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of All Pregnant Women for Hepatitis B Surface Antigen*, 37 MORBIDITY & MORTALITY WKLY. REP. 342 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm>.

217. *Id.*

Thus by 1988, ACIP had proposed a solution to address potential hepatitis B transmission to approximately 3500 infants annually.

2. The 1991 ACIP Recommendation

In 1991, after the NCVIA was in effect, ACIP changed its recommendation dramatically. Now, instead of characterizing the United States as “an area of low HBV prevalence”²¹⁸ with certain high risk groups, ACIP describes the situation this way: “The acute and chronic consequences of hepatitis B virus infection are major health problems in the United States.”²¹⁹ While acknowledging that “most infections occur among adults and adolescents,” ACIP decided “immunization with hepatitis B vaccine is the most effective means of preventing HBV infection and its consequences.”²²⁰ ACIP’s recommendation was a “comprehensive strategy to eliminate transmission of HBV and ultimately reduce the incidence of hepatitis B and hepatitis B-associated chronic liver disease in the United States.”²²¹

To achieve this end, ACIP recommended hepatitis vaccination for all infants, regardless of the mother’s infection status. It stated that “[h]epatitis B vaccine should be incorporated into vaccination schedules for children. The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of age.”²²²

The 1991 recommendation noted two types of licensed hepatitis B vaccines in the United States, Merck’s Recombivax HB and GlaxoSmithKline’s Engerix-B, both produced with new, genetically engineered recombinant DNA technology.²²³ As to safety, the report stated that the vaccines “have been shown to be safe,” “over 4 million adults have been vaccinated,” and that “many children have received hepatitis B vaccine worldwide.”²²⁴ It noted however, that “only a small number of children have received recombinant vaccine.”²²⁵ Indeed,

218. *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, *supra* note 213.

219. Ctrs. for Disease Control & Prevention, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 MORBIDITY & MORTALITY WKLY. REP., Nov. 22, 1991, at 1, 2, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>; see also ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY 211-35 (Kathleen R. Stratton et al. eds., 1994), available at <http://www.nap.edu/catalog/2138.html> (addressing safety and reported adverse events for hepatitis B vaccine administration).

220. Ctrs. for Disease Control & Prevention, *supra* note 219, at 3.

221. *Id.*

222. *Id.* at 12.

223. *Id.* at 6.

224. *Id.* at 10.

225. *Id.* at 11.

the package inserts for Recombivax HB and Engerix-B indicated that the clinical trials for the vaccines had been done on small groups of children, and gave scant evidence that the trials had been done on newborn infants.²²⁶

In addition to recombinant DNA, which had not been used previously on a widespread basis, the hepatitis B vaccine administered at birth from 1990 to 2001 included 25 micrograms of the mercury-containing preservative thimerosal,²²⁷ or 12,500 parts per billion (ppb) of ethylmercury (because thimerosal is half mercury by weight).²²⁸ Mercury is a recognized neurotoxin, with an amount as low as 0.5 ppb able to destroy human neuroblastoma cells.²²⁹ The vaccine today continues to contain 0.3 ppb thimerosal, or what the CDC denotes as a “trace” amount.²³⁰ Both approved vaccines also contain aluminum as an adjuvant to

226. Merck & Co., *Recombivax HB: Hepatitis Vaccine*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf> (insert for Recombivax HB). Merck’s Recombivax HB package insert currently provides the following information about clinical trials that occurred before marketing: “In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose.” The insert does not state the ages of the children or the proportion of the 147 subjects who were infants. It makes no mention of newborns. See also GlaxoSmithKline, *Engerix-B*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf> (insert for Engerix). GlaxoSmithKline (GSK) Engerix-B package insert provides this information: “In 36 clinical studies, a total of 13,495 doses of ENGERIX-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration.” While GSK suggests that it did test the vaccine in healthy newborns, it provides no number of them on which the vaccine was tested nor does it clarify how many adults vs. how many children tested the vaccine.

227. See *Thimerosal in Vaccines, Thimerosal as a Preservative*, *supra* note 138.

228. NAT’L RESEARCH COUNCIL, TOXICOLOGICAL EFFECTS OF METHYLMERCURY 11 (2000) (citing the Environmental Protection Agency’s guideline of 0.1 microgram per kilogram per day). Thus a baby weighing approximately five kilograms at two months should not receive more than 0.5 micrograms of mercury on the day of a doctor’s visit. At the two-month visit, infants routinely received 62.5 micrograms of mercury, or 125 times the EPA limit. Later studies suggested that “the accepted reference dose should be lowered to between 0.025 and 0.06 micrograms per kilogram per day,” meaning that the exposure at the two-month visit could be as high as 500, rather than 125, times the recommended level. Steven G. Gilbert & Kimberly S. Grant-Webster, *Neurobehavioral Effects of Developmental Methylmercury Exposure*, 103 ENVTL. HEALTH PERSP. 135 (1995).

229. Michael F. Wagnitz, Comment to Rahul K. Parikh, *Fighting for the Reputation of Vaccines: Lessons from American Politics*, 121 PEDIATRICS 621 (2008), available at http://pediatrics.aappublications.org/content/121/3/621/reply#pediatrics_el_36839.

230. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226. In its list of excipients, the CDC states: “Where thimerosal is marked with an asterisk (*) it indicates that the product should be considered equivalent to thimerosal-free products. This vaccine may contain trace amounts (<0.3 mcg) of mercury left after post-production thimerosal removal, but these amounts have no biological effect.” *Vaccine Excipient & Media Summary, Part 2: Excipients Included in U.S. Vaccines*, by Vaccine, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 17, 2011), <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>. The FDA considers Recombivax HB and Engerix-B products thimerosal-free. See *Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm> (last updated Mar. 31, 2010) (“New pediatric

boost immune response.²³¹ Like mercury, aluminum is also a recognized toxic substance²³² and both metals potentially stimulate autoimmune syndromes.²³³

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 . . . as safe was inadequate and flawed, information on alternative preservatives was ignored, the vaccine manufacturers ignored a significant body of knowledge on health effects for at least 50 years and that the vaccine manufacturers did not conduct necessary toxicology studies to establish safety.²³⁴

Besides the mercury safety concern, the Engerix-B and Recombivax HB inserts do not address the safety of simultaneous vaccine administration.²³⁵ This is notable because ACIP recommends that the second and third doses of hepatitis B vaccine be given with the diphtheria, tetanus and pertussis vaccine, the *Haemophilus influenza* type b vaccine, the pneumococcal vaccine and inactivated poliovirus vaccine. Although it recommends simultaneous administration of vaccines, ACIP does not require that childhood vaccines be clinically tested for synergistic effects.

The Association of American Physicians and Surgeons filed a Freedom of Information Act (FOIA) in 1999 to require information on the hepatitis B vaccine preliminary safety data. It requested all safety data the CDC had prior to ACIP's 1991 recommendation and the statistical model ACIP used to assure safety.²³⁶ It

formulations of hepatitis B vaccines have been licensed by the FDA, Recombivax-HB (Merck, thimerosal free) in August 1999 and Engerix-B (GlaxoSmithKline, thimerosal free) in January 2007.”).

231. *Vaccine Excipient & Media Summary, Part 2: Excipients Included in U.S. Vaccines*, by *Vaccine*, *supra* note 230.

232. For neurotoxic effects of mercury, see *Mercury: Human Health*, ENVTL. PROTECTION AGENCY, <http://www.epa.gov/mercury/health.htm> (last updated Oct. 1, 2010), and for aluminum, see *Division of Toxicology and Environmental Medicine ToxFAQs*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY (Sept. 2008), <http://www.atsdr.cdc.gov/tfacts22.pdf>.

233. E. Israel et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Lucette Pelletier et al., *Autoreactive T Cells in Mercury-Induced Autoimmunity: Ability To Induce the Autoimmune Disease*, 140 J. IMMUNOLOGY 750 (1988); Yehuda Shoenfeld & Nancy Agmon-Levin, ‘ASIA’ – *Autoimmune/Inflammatory Syndrome Induced by Adjuvants*, 36 J. AUTOIMMUNITY 4 (2010); Ellen K. Silbergeld et al., *Mercury and Autoimmunity: Implications for Occupational and Environmental Health*, 207 TOXICOLOGY & APPLIED PHARMACOLOGY 282 (2005); L. Tomljenovic & C. A. Shaw, *Aluminum Vaccine Adjuvants: Are They Safe?*, 18 CURRENT MEDICINAL CHEMISTRY 2630 (2011).

234. George W. Lucier, *Thimerosal Is a Developmental Neurotoxicant*, VERMONTERS FOR A CLEAN ENV'T, <http://www.vtce.org/mercury/lucier.pdf> (last visited Nov. 9, 2011).

235. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226.

236. *The Hepatitis B Vaccine: Helping or Hurting Public Health: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Res. of the H. Comm. on Gov't Reform*, 106th Cong. 260 (1999) [hereinafter *Hepatitis Hearings*] (statement of Barbara Loe Fisher).

has never received a response to its request made more than ten years ago.²³⁷

By 1999, several scientific studies questioned the merits of the program to vaccinate infants and newborns against hepatitis B. A 1996 article in the *Journal of Autoimmunity* concluded, “[t]here is no doubt that the new recombinant hepatitis B vaccine is different from mumps, measles, and rubella vaccines in its ability to trigger autoimmunity.”²³⁸ A 1999 study in *Epidemiology* found a positive association between hepatitis B vaccination and liver disease in children under age six.²³⁹ The article “question[s] the logic of universal infant HB vaccination in the United States.”²⁴⁰ It further states, “[t]here is no evidence . . . supporting a protective effect of the HB vaccine against liver problems for the general population of U.S. children.”²⁴¹ It concludes that “[e]ven if the HB vaccine is effective for high risk groups, it does not indicate that it is also effective for negligible risk groups.”²⁴²

Another article reported, “In the case of Sweden, vaccinating over 100,000 children annually to ideally avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint.”²⁴³ In other words, in their calculus, it was irrational to vaccinate 1000 people to prevent illness in 2. To compare this to the U.S. context, according to ACIP, approximately 3500 infants were considered to be at risk of hepatitis in 1988 and only 15% of them at most, or 525 infants, would not have been successfully treated through hepatitis B immune globulin treatment and vaccination. According to this information, the United States now vaccinates approximately 4 million infants per year to prevent approximately 525 cases of likely infection, or about 10,000 infants to prevent likely illness in one child.

3. The 1999 ACIP Recommendation

In January 1999, ACIP expanded its hepatitis B vaccination recommendation to include “all unvaccinated children aged 0-18 years and made hepatitis B vaccine available through the Vaccines for Children program (VFC) for persons

237. Michael Belkin, *The Vaccine Bubble and the Pharmaceutical Industry*, in VACCINE EPIDEMIC 139 (Louise Kuo Habakus & Mary Holland eds., 2011) (“We are still waiting for a response today. Their failure to respond is damning. The implication is that the at-birth hepatitis B vaccine recommendation was made without conducting proper safety studies in babies beforehand.”).

238. Arnon Dov Cohen & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity*, 9 J. AUTOIMMUNITY 699, 701 (1996).

239. Monica A. Fisher & Stephen A. Eklund, *Hepatitis B Vaccine and Liver Problems in U.S. Children Less Than 6 years Old, 1993 and 1994*, 10 EPIDEMIOLOGY 337 (1999).

240. *Id.* at 339.

241. *Id.*

242. *Id.*

243. Sten Iwarson, *Why the Scandinavian Countries Have Not Implemented Universal Vaccination Against Hepatitis B*, 16 VACCINE S56 (1998).

aged 0-18 years who are eligible for VFC.”²⁴⁴ This new policy expanded the recommendation from just infants, covering about 4 million newborn infants per year, to include all children through eighteen years, or approximately 76 million children under age 18 who would each be recommended or required to get three doses of the vaccine, or about 228 million doses. Under the VFC, all children would be eligible for the vaccine; doctors could provide them to families without charge because of federal and state subsidies.²⁴⁵

Congress held hearings on the hepatitis B vaccine in May 1999. Doctors, nurses, and parents of children injured by the hepatitis B vaccine testified. The testimonies suggested that the vaccine’s side effects vastly outweighed the threat of the disease to young children.²⁴⁶ The speakers expressed alarm at the apparent rise in vaccine-related neurological disorders, deaths, and also at the decision-making process that had led to hepatitis B vaccination without representation.²⁴⁷

On July 8, 1999, the U.S. Public Health Service and the American Academy of Pediatrics issued a joint statement recommending reduced infant exposure to thimerosal, the mercury-containing preservative then used in the hepatitis B vaccines. It specifically recommended that the birth dose of the vaccine should be postponed in infants whose mothers were not hepatitis B positive until two to six months of age.²⁴⁸ By mid-September 1999, however, when the hepatitis B vaccines became available without thimerosal as a preservative, although it still contained “trace” amounts, the Public Health Service returned to its prior recommendation to administer the first dose of hepatitis B vaccine to newborns.²⁴⁹

4. The 2005 ACIP Recommendation

In 2005, ACIP strengthened its hepatitis B recommendation further, stating that “[a]ll delivery hospitals should implement standing orders for administration of hepatitis B vaccination as part of routine medical care of all medically stable

244. Ctrs. for Disease Control & Prevention, *Notice to Readers Update: Recommendations To Prevent Hepatitis B Virus Transmission -- United States*, 48 MORBIDITY & MORTALITY WKLY. REP. 33 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056293.htm>.

245. *VFC: For Parents*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/programs/vfc/parents/default.htm> (last updated Oct. 19, 2011) (“The Vaccines for Children (VFC) Program offers vaccines at no cost for eligible children through VFC-enrolled doctors.”).

246. *Id.*

247. *Hepatitis Hearings*, *supra* note 236, at 67 (statement of Michael Belkin).

248. Ctrs. for Disease Control & Prevention, *Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, 48 MORBIDITY & MORTALITY WKLY. REP. 563 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4826a3.htm>.

249. Ctrs. for Disease Control & Prevention, *Notice to Readers: Availability of Hepatitis B Vaccine That Does Not Contain Thimerosal as a Preservative*, 48 MORBIDITY & MORTALITY WKLY. REP. 780, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4835a3.htm>.

infants weighing greater than or equal to 2000 g at birth.”²⁵⁰ This 2005 ACIP report also noted that 15-50% of children “have low or undetectable concentrations of anti-HBs (anti-HBs loss) [hepatitis B antibodies] 5-15 years after vaccination.”²⁵¹ Although the report asserted that these children would likely develop an antibody response upon exposure to HBV, it stated that the children did not have documented immunity 5-15 years after vaccination. Vaccination decisions are typically made on the basis of documented immunity. In other words, at the age of sexual maturity when the children might themselves benefit from the vaccine’s protection, its efficacy might not exist. This ACIP report also rejected any purported association between the vaccine and multiple sclerosis, chronic fatigue syndrome, neurologic disorders, rheumatoid arthritis, type 1 diabetes, autoimmune disease, and sudden infant death syndrome that had been described in the scientific literature.²⁵²

Since 2005, further scientific investigation has suggested severe deleterious health consequences for many children from the hepatitis B vaccine. A 2008 study associates hepatitis B vaccination of male newborns with autism diagnoses from 1997-2002.²⁵³ Boys who received the birth dose of hepatitis B vaccine were three times more likely to have parental report of autism than those who had not received the hepatitis B birth dose.²⁵⁴ Gallagher and Goodman also found that the three dose series of hepatitis B vaccines were associated with a nine-fold risk for the vaccinated male newborns to have received early intervention or special education services.²⁵⁵ Data acquired from the CDC’s Vaccine Safety Datalink under a Freedom of Information Act request also show an association between vaccinations given before one month of age and autism and other neurological disorders.²⁵⁶ A 2011 study of the hepatitis B vaccine on mice demonstrates that it changes gene expression in the liver “which reflected subtoxic/adverse effects of

250. Ctrs. for Disease Control & Prevention, *supra* note 4, at 14.

251. *Id.* at 10.

252. *Id.* at 11.

253. Carolyn M. Gallagher & Melody S. Goodman, *Hepatitis B Vaccination of Male Neonates and Autism Diagnosis, NHIS 1997-2002*, 73 J. TOXICOLOGY & ENVTL. HEALTH PART A 1665 (2010).

254. *Id.*

255. Carolyn M. Gallagher & Melody S. Goodman, *Hepatitis B Triple Series Vaccine and Developmental Disability in U.S. Children Aged 1-9 Years*, 90 TOXICOLOGICAL & ENVTL. CHEMISTRY 997 (2008).

256. *A Brief Review of Verstraeten’s “Generation Zero” Vaccine Safety Datalink Study Results*, SAFE MINDS (2004), <http://www.safeminds.org/research/library/GenerationZeroNotes.pdf>; *Generation Zero, Thomas Verstraeten’s First Analyses of the Link Between Vaccine Mercury Exposure and the Risk of Diagnosis of Selected Neuro-Developmental Disorders Based on Data from the Vaccine Safety Datalink: November-December 1999*, SAFE MINDS (2004) <http://www.safeminds.org/research/library/GenerationZeroPowerPoint.pdf> (showing significant correlation between early mercury exposures and autism, attention deficit disorder and sleep disorders).

the vaccine, especially in subtle liver injury.”²⁵⁷ The authors attributed these adverse effects to aluminum included in the vaccine as an adjuvant.²⁵⁸

ACIP’s hepatitis B recommendations remain in effect today, with the first dose recommended before hospital discharge, the second between one and two months, and the third between six and eighteen months.²⁵⁹ The hepatitis B vaccines continue to contain aluminum and trace amounts of mercury. Forty-seven states make the hepatitis B vaccine mandatory for daycare and preschool.²⁶⁰

Critics continue to question the rationality of this vaccination mandate for young children. First, newborns are at almost no risk of hepatitis B. According to one doctor, when the U.S. population was around 248 million in 1991, there were 18,003 reported cases of hepatitis B viral illness in total—a national incidence of 0.007%.²⁶¹ The number of cases of hepatitis B in the United States peaked in 1985 and started to decline because of improved precautions. In 1986, five years before the 1991 ACIP Recommendation, only 279 cases of HBV infection were reported nationwide in children under age fourteen.²⁶² By contrast, as of June 2006, there were 47,198 reports to the Vaccine Adverse Event Reporting System (VAERS) describing complications following the administration of the hepatitis B vaccine alone or with other vaccines. Of these, 23,406 were for children fourteen years of age and younger. There were 909 death reports, of which 795 were under the age of fourteen.²⁶³ Dr. David Kessler, former commissioner of the FDA, wrote in the *Journal of the American Medical Association* that “only about 1% of serious adverse events are reported to the FDA,”²⁶⁴ suggesting that the number of reported vaccine-related injuries may be underestimated.

In his 1999 testimony before the U.S. Congress, Mr. Belkin stated “only 54 cases of the disease were reported to the CDC in the 0-1 age group.”²⁶⁵ In the same year, there were 1080 reports of adverse events reported in the 0-1 age group, with 47 deaths. “Total VAERS hepatitis B reports for the 0-1 age group

257. Heyam Hamza et al., *In Vivo Study of Hepatitis B Vaccine Effects on Inflammation and Metabolism Gene Expression*, MOLECULAR BIOLOGY REP., Mar. 17, 2011.

258. *Id.* at 6.

259. *Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States, 2011*, *supra* note 1.

260. *See Hepatitis B Prevention Mandates for Daycare and K-12*, *supra* note 2.

261. F. Edward Yazbak, *The Hepatitis B Vaccine: What Went Wrong?*, VACCINATION NEWS, <http://www.vaccinationnews.com/node/19957> (last visited Dec. 2, 2011).

262. *Id.*

263. *Id.*

264. David Kessler et al., *Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Events and Product Problems*, 269 JAMA 2765, 2765 (1993) (“Only about 1% of serious events are reported to the FDA, according to one study.”).

265. *Hepatitis Hearings*, *supra* note 236, at 67 (statement of Michael Belkin).

outnumber reported cases of the disease 20 to 1.”²⁶⁶ If these reports in fact reflected about 1% of total adverse reactions to the vaccine, as is conceivable, the number of vaccine injuries to disease cases would be closer to 2000 to 1.

Mr. Belkin wrote:

Clearly, the interests of newborn babies were not represented on the original panel that created this vaccination policy in 1991. This vaccine has no benefit whatsoever for newborns, in fact it wears off and they will need booster shots later in life when they actually could get exposed to the disease. This is simply a case of ravenous corporate greed and mindless bureaucracy teaming up to overwhelm common sense.²⁶⁷

B. Financial Considerations in Hepatitis B Vaccination Mandates

The incidence of the disease was already diminishing when ACIP made its 1991 recommendation for newborns. While public health officials found it challenging to vaccinate the at-risk adult populations, they were already succeeding at vaccinating the at-risk infants of infected mothers. The rationale to vaccinate the whole population of infants and young children in order to avoid later incidence of the disease among the adult population was unproven. Infants have been exposed to unknown risks for decades because of inadequate safety science. The public health rationale for the hepatitis B vaccination of newborns, infants, and young children is weak.

Financial motivation for the recommendation, however, is strong. The vaccination of four million infants per year yields a substantial annual income stream in the hundreds of millions of dollars.²⁶⁸ After the liability protections for industry and the medical profession were in place under the NCVIA, there were substantial incentives for industry to work with government to introduce new universal childhood vaccination mandates. NCVIA’s liability protection mitigated the risks to industry from new, relatively untested vaccines. Infants in the hospital after birth were available for medical intervention; additional doses could be given at regularly scheduled pediatric visits. Given the way the courts had interpreted *Jacobson*, few in government or industry would have feared a

266. *Id.*

267. Michael Belkin, *Mindless Vaccination Bureaucracy*, NAT’L VACCINE INFO. CTR., <http://www.nvic.org/vaccines-and-diseases/Hepatitis-B/fatherstory.aspx> (last visited Dec. 2, 2011).

268. See, e.g., BUSINESS INSIGHTS, *THE VACCINE MARKET OUTLOOK: MARKET ANALYSIS OF FUTURE GROWTH AND FUTURE PLAYERS BY SECTOR* 39 tbl. 2.2 (2005). The report indicates that the total U.S. revenue from hepatitis B vaccines in 2002 was \$499.6 million and \$468.1 in 2003. The report does not disaggregate the revenue from infant, childhood, and adult hepatitis B vaccines or from the hepatitis A vaccine, so the information is imprecise. The report does discuss, however, the importance of compulsory vaccination to the vaccine market. “What is evident from th[ese] data is that for a vaccine brand or category to perform well in the US market, it is essential that it is included in the US immunization schedule.” *Id.* at 38.

constitutional challenge. Indeed, two cases challenging the hepatitis B vaccination mandates on religious grounds lost.²⁶⁹

Part of *Jacobson's* rationale for deference to state legislatures was their representative nature; legislatures by their nature must take account of differing views. If the legislature makes bad choices, the electorate can reverse those choices and unseat the legislators through popular elections. But ACIP has become the driving force behind vaccination mandates, a federal advisory body with almost no public participation and no direct accountability to voters.²⁷⁰ Because of this change in the locus of real decision making from legislators to ACIP, there are far greater risks of conflicts of interest. ACIP advisers have strong ties to industry, and financial and professional self-interest may outweigh public health in their decision-making.

In 2000, a Congressional report on *Conflicts of Interest in Vaccine Policy Making* identified notable conflicts of interest in the FDA and CDC advisory bodies that make national vaccine policy.²⁷¹ 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 in infants.²⁷² Merck voluntarily withdrew Rotashield from the market thirteen months after its launch due to serious adverse reactions.²⁷³ The House Government Reform Committee found numerous problems with Rotashield's approval and vaccine approvals in general:

advisers' financial ties to vaccine manufacturers;
pervasive conflicts of interest;
little unbiased public participation;
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.²⁷⁴

There is little evidence that the CDC or FDA implemented any of Congress's recommendations. In 2008, eight years later, a government study of

269. *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002); *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (E.D. Ark. 2002).

270. *Hepatitis Hearings*, supra note 236, at 67 (statement of Michael Belkin).

271. STAFF OF H. COMM. ON GOV'T REFORM, 106TH CONG., *CONFLICTS OF INTEREST IN VACCINE POLICY MAKING* (Comm. Print 4024), available at <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.").

272. *Id.*

273. *Id.*

274. *Id.*

disclosure and conflict waivers at the CDC found that ninety-seven percent of Special Government Advisers on CDC committees failed to disclose necessary information,²⁷⁵ prompting criminal investigation of some.²⁷⁶

Illustrative of the culture of conflicts of interest is the former Director of the CDC, Dr. Julie Gerberding. One year after she stepped down as CDC Director, she joined Merck as the Director of its Vaccine Group.²⁷⁷ During her tenure at CDC, ACIP approved Merck's Gardasil vaccine for human papilloma virus (HPV) against cervical cancer.²⁷⁸ Gardasil is the most expensive childhood 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 of the HPV vaccine in 2007, the Vaccine Adverse Event Reporting System (VAERS) has recorded 23,388 adverse events, including 103 deaths and 4777 individuals who have not recovered after HPV vaccination.²⁷⁹

The financial motivations in vaccine recommendations and mandates are manifold. Industry offers ACIP members and other regulators career and financial incentives. Industry offers financial inducements to state legislators who make ACIP recommendations mandatory. States receive federal funding for vaccination mandates. Doctors generate revenue from additional pediatric visits

275. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GEN., OEI-04-07-00260, CDC'S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES 16 (2009).

276. *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.").

277. *Dr. Julie Gerberding Named President of Merck Vaccines*, MERCK (Dec. 21, 2009), https://merck.com/newsroom/news-release-archive/corporate/2009_1221.html.

278. Lauri E. Markowitz et al., Ctrs. for Disease Control & Prevention, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MORBIDITY & MORTALITY WKLY. REP., Mar. 12, 2007, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm>.

279. *VAERS Data*, VACCINE ADVERSE EVENT REPORTING SYS., <http://vaers.hhs.gov/data/index> (last visited Dec. 2, 2011); see also Mark Blaxill, *A License To Kill? Part 1: How a Public-Private Partnership Made the Government Merck's Gardasil Partner*, AGE OF AUTISM (May 12, 2010, 5:35 AM), <http://www.ageofautism.com/2010/05/a-license-to-kill-part-1-how-a-public-private-partnership-made-the-government-mercks-gardasil-partner.html>; Mark Blaxill, *A License To Kill? Part 2: Who Guards Gardasil's Guardians?*, AGE OF AUTISM (May 12, 2010, 5:37 AM), <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*, AGE OF AUTISM (May 13, 2010, 5:45 AM), <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>; *Online Access to the U.S. Government's VAERS Data*, NAT'L VACCINE INFO. CTR., <http://www.medalerts.org> (last visited Dec. 2, 2011); SANE VAX, INC., <http://sanevax.org> (last visited Dec. 2, 2011).

and from the vaccinations themselves. A “more is better” vaccination policy has many financial rewards, but does not necessarily lead to optimal or even rational public health outcomes.

While observers have long noted conflicts of interest in vaccination mandates, what is new is the potential scale of such conflicts. Because all school children in the country are now subject to ACIP vaccination recommendations, and state mandates based on them, conflicts of interests have greater impact than when mandates were local affairs. The NCVIA, which centralized national vaccination policy and created its infrastructure, facilitated vastly greater effect, both good and bad.

C. Informed Consent, or Lack Thereof, to Hepatitis B Vaccination

The norm of informed consent in medicine requires doctors to provide extensive information about the known risks of interventions to patients and to allow them to make the ultimate decisions.²⁸⁰ Similarly, drug manufacturers are required by law to provide accurate and complete information about drug risks with their products. With respect to vaccines, however, these norms are substantially relaxed. The NCVIA 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 and requires that manufacturers provide proper warnings to doctors only, who are considered to be “learned intermediaries.”²⁸¹ Both industry and the medical community lobbied for this lowered standard.²⁸²

The NCVIA initially required more information than what parents receive today. It specified ten items for CDC-drafted Vaccine Information Materials (VIMs).²⁸³ The initial versions were twelve pages long and required parental signature. But pediatricians found the brochures were scaring parents and took too much time.²⁸⁴ The American Academy of Pediatrics submitted legislation to shorten the VIMs and Congress enacted the proposed changes in 1993. Instead of ten information items, statements for parents now contained four: the benefits of

280. 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.”).

281. 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.”).

282. See COLGROVE, *supra* note 106, at 208-17.

283. 42 U.S.C. § 300aa-26(c) (2006).

284. Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & L. 249, 270-71 (1996).

the vaccine, the risks, one sentence about the VICP, and a reference to the CDC for further information. Parents' signatures were also eliminated. In an advisory to doctors, the CDC wrote that the new VIMs "provide enough information that anyone reading the materials should be adequately informed."²⁸⁵ The current statements largely reassure parents that immunizations are safe and effective.

The current Hepatitis B Vaccine Information Statement provides the following information about possible adverse events, claiming, "Hepatitis B is a very safe vaccine. . . . Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses. A vaccine, like any medicine, *could* cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small."²⁸⁶

By contrast, the hepatitis B vaccine package inserts provide long lists of adverse events reported since the vaccine entered the market. A partial list of adverse events reported for Engerix-B and Recombivax HB include anaphylaxis, encephalitis, encephalopathy, paralysis, optic neuritis, multiple sclerosis, and vasculitis.²⁸⁷

Under the vaccine laws before 1986, these Vaccine Information Statements would not have met minimum requirements for duty to warn. Some parents and caregivers today also find the statements insufficient for rational decision-making and informed consent. In Oregon, for instance, a bill has been introduced in the state legislature to require physicians to give parents the hepatitis B vaccine package insert and to have them consent in writing so that they can better appreciate the risks.²⁸⁸ The citizen who took this initiative is the grandmother of an infant who suffered a severe stroke after hepatitis B vaccination.

D. A Hypothetical Challenge to the New York State Hepatitis B Vaccine Mandate for Preschoolers

So how would the Supreme Court today evaluate a challenge to New York State's hepatitis B vaccination mandate for preschoolers? The Court would likely have to address the following issues based on its public health and personal autonomy precedents.

1. Public Health Necessity

The Court would have to decide if there is a sufficient public health necessity for the state to impose a preschool vaccination mandate. While the

285. *Id.* at 272.

286. *Hepatitis B Vaccine: What You Need To Know*, CENTERS FOR DISEASE CONTROL & PREVENTION (July 18, 2007), <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf>.

287. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226.

288. H.R. 2635, 76th Leg. Assemb., 2011 Reg. Sess. (Ore. 2011), *available at* <http://gov.oregonlive.com/bill/2011/HB2635>.

Court would be highly deferential, it would not grant a blank check. Although the population as a whole may face the necessity to prevent and reduce the prevalence of hepatitis B, the state would likely have to show that the necessity specifically pertains to preschool children, the population to be burdened with vaccination risks. As Dr. Jacobs has suggested, “The absence of linkage of a disease to school activities should weigh heavily against a vaccination requirement.”²⁸⁹ As young children are presumably not engaged in high risk transmission activities in preschool, on or off school premises, and there is substantial evidence of potential medical harm to them based on science and adverse vaccine event reporting, the state’s rationale of necessity is questionable.

2. Reasonable Means

The Court would have to assess if a vaccination mandate for preschoolers is a reasonable means of addressing the threat of hepatitis B prevalence in the broader society. Assume that the trial record revealed minimal clinical trials of the vaccine on newborn infants and young children, including extremely short monitoring periods.²⁹⁰ Assume that empirical evidence showed that the adverse effects on this age group were greater than the risks posed by the illness.²⁹¹ Assume that the evidence showed that the vaccine’s efficacy wore off before puberty and that preschoolers would require booster shots by age twelve to maintain protection against the disease.²⁹² While the state would point to the vaccine’s approvals by the FDA and ACIP as evidence of reasonableness, these regulatory affirmations would not end constitutional inquiry. No jurisprudence of which the author is aware suggests a presumption of reasonableness based on agency approval.

3. Proportionality

The Court would have to assess whether the New York State vaccination mandate is proportionate to the risk of disease. The state would have to show that the risks of the disease to these children outweigh the risks of the vaccine. Most likely, this would be very difficult to prove since incidence of the disease in the preschool population is exceedingly low, yet the risks of adverse events from the vaccine, including anaphylaxis, encephalopathy, and death, are well-documented.²⁹³ Furthermore, the public health rationale for the preschool mandate was never primarily to reduce disease solely in this age group; rather, it was to prevent risks to the entire population. It is unlikely that a court would be

289. Jacobs, *supra* note 34, at 193.

290. *See supra* notes 219-226 and accompanying text.

291. *See supra* notes 264-287 and accompanying text.

292. *See supra* notes 249-251 and accompanying text.

293. *See supra* notes 264 - 287 and accompanying text.

willing to see the benefits to preschoolers as proportionate to the risks.

4. Harm Avoidance

The state would have to show that it provides for harm avoidance in its hepatitis B mandate. In other words, it would have to demonstrate that it offers a fair process for allowing medical exemptions to those who are at risk of injury or death from the vaccine. A federal policy that recommends newborn vaccination makes harm avoidance almost impossible, despite the fact that this is one of *Jacobson's* core requirements. How parents and doctors can avoid harm to a newborn, who has virtually no medical history at birth, is hard to fathom except by avoiding neonatal medical intervention altogether.

If (1) harm avoidance is an essential element to the state's right to compel vaccination (as *Jacobson* concluded), while (2) the administration of vaccines may prevent any meaningful opportunity for harm avoidance because the infant's health status is unknown, then one may question whether the harm avoidance criterion is met. While day of birth administration is not strictly required for preschool attendance, the federal newborn recommendation tries to ensure that the mandate is followed.²⁹⁴ In forty-seven states, the mandate is compulsory, and for all infants, day of birth administration is recommended.

5. Non-discrimination

The Court would have to assess whether the vaccination mandate is non-discriminatory. The state would argue that because the mandate is imposed on all children in the same way, it is non-discriminatory. The parents would argue that while *Zucht* upholds the right of a school district or state to impose vaccination mandates on school children exclusively, that right is limited. If a vaccination mandate is imposed without any rational relation to an educational purpose and is based on population-wide necessity, its application may be arbitrary. If the mandate is imposed solely on young children not primarily for their benefit, its non-discrimination is questionable.

6. Liberty Interest in Due Process

The Court would have to assess whether parents, on behalf of their child,

294. Even though newborn administration of the hepatitis B vaccine is the standard of care, forty percent of infants do not receive the birth dose. The mothers of these infants have higher levels of income and education. Sean O'Leary, *Risk Factors for Non-Receipt of Hepatitis B Vaccine in the Newborn Nursery*, Centers for Disease Control & Prevention (Mar. 29, 2011, 11:15 AM), <http://cdc.confex.com/cdc/nic2011/webprogram/Paper25335.html> ("64,425 infants were identified in the birth cohort, of whom 39,703 (61.6%) received a birth dose of HBV. . . . Maternal characteristics such as higher income, higher education, and white race are associated with non-receipt of the HBV during the perinatal period.").

have a liberty interest in being able to refuse an unwanted medical intervention. The Court would likely acknowledge that any compulsory medical intervention, including childhood vaccination, is “a substantial interference with that person’s liberty.”²⁹⁵ Having acknowledged that there are limits to the imposition of unwanted medical treatment on a prisoner in *Harper*, the Court would likely recognize an analogous liberty interest in a young child, which the child’s parents exercise as guardians. The Court has repeatedly acknowledged that the right to bodily integrity and to refuse unwanted medical treatment is deeply rooted in the historical traditions of the United States. To be sure, vaccination against infectious disease raises concerns different from a medical intervention that would affect only the individual. But the deeply rooted interest in bodily integrity exists in both contexts.

Jacobson acknowledged that the right to bodily integrity is not absolute but that the state may not impermissibly burden that right. In *Harper*, the Court recognized that the psychotropic drugs administered to a prisoner had to be related to legitimate penological interests.²⁹⁶ While there is a distinction between forcible injection of a prisoner and compelled injection of a preschooler, the difference may be more theoretical than real. New York does not assert the right to force vaccination on preschoolers, but it does assert the right to withhold education and to require vaccination even if a child is homeschooled. The Court would need to elaborate what constitutes an “impermissible burden” or “undue burden” on the child’s liberty interest if it found that New York’s statute interfered excessively with the child’s liberty interest.

Although courts have interpreted the required nexus between vaccination mandates and education to be slight since *Zucht*, the Court would have to examine whether some connection must exist between the disease and transmission at school. In this case, the parents would argue that there is no nexus, no threatened disruption of attendance, and a better available means, *i.e.* screening mothers and vaccinating only those infants at risk of hepatitis B infection. The state would argue that no nexus is required under expansive interpretations of *Jacobson*.

Some of the Justices who participated in the personal autonomy decisions, notably Justices Stevens, Brennan, Marshall, and Blackmun,²⁹⁷ would likely have found the right to refuse vaccination to be a “fundamental” right and would have subjected the state’s statute to “strict scrutiny.” These Justices likely would have required that any state statute be narrowly tailored to obtain its compelling state interest. As Justice Stevens concurred in *Glucksberg*, the right to refuse medical treatment stems not just from the common law but also from the rights to bodily

295. *Washington v. Harper*, 494 U.S. 210, 229 (1990).

296. *Id.* at 223.

297. *See supra* notes 166-193 and accompanying text.

integrity and dignity.²⁹⁸ Justice Stevens would likely have argued that the right to bodily integrity is fundamental.²⁹⁹

Subjected to strict scrutiny, the Court would likely find the vaccination mandate unconstitutional. It is not clear that prevention of hepatitis B in the preschool population is a compelling state interest, particularly when children are at negligible risk, and there is no mandate for the adult population. Similarly, it is not clear that a preschool mandate is narrowly targeted to achieve the state interest of eradicating hepatitis B viral disease. Given poor evidence that children's immunity persists into puberty, it would be difficult for the state to prove its case. Neither the federal government nor states have alleged that disease transmission among preschoolers is a serious threat to public health.

It seems doubtful that there would be much readiness on the Court today to adopt a strict scrutiny standard of review for a state vaccination mandate, however. As Justice Scalia chided the majority in *Lawrence v. Texas*, the Justices in the majority seemed to be more ready to "apply an unheard-of form of rational-basis review" than to declare a new interest "fundamental."³⁰⁰ Under intermediate scrutiny or even rational basis, though, the state must demonstrate that its mandate is rational. If the petitioner can prove that the vaccine causes more harm than it prevents to this population, the mandate might not meet even the rational basis test.

7. Liberty Interest in Equal Protection

A vaccination mandate for hepatitis B exclusively for young children, when none is imposed on the adult population, raises equal protection issues when the state's objective is eradication of hepatitis B viral disease from the population as a whole. While *Zucht* decided that schools may impose mandates for infectious diseases, there are constitutional limits to what a legislative majority may impose on any minority while leaving itself free of such constraints. While the state might argue that children are at risk from the disease and benefit from its compulsion, a child petitioner might argue that the adult population, which is demonstrably at far greater risk, is exempted from a universal mandate in violation of equal protection. Children may be the subject of discrimination if they are selectively vaccinated for a disease from which they are at negligible risk. While the hepatitis B mandate for children raises both due process and equal protection concerns, one could imagine a Justice deciding that the regulation meets a rational basis or intermediate scrutiny test but fails equal protection. Justice O'Connor followed this rationale in *Lawrence v. Texas*.³⁰¹

298. *Washington v. Glucksberg*, 521 U.S. 702, 741-43 (1997) (Stevens, J., concurring).

299. *Id.*; *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 331-34 (1990) (Stevens, J., dissenting); *Harper*, 494 U.S. at 237-39 (Stevens, J., concurring in part and dissenting in part).

300. *Lawrence v. Texas*, 539 U.S. 558, 586 (2003) (Scalia, J., dissenting).

301. *Id.* at 579-80.

CONCLUSION

Although courts have interpreted *Jacobson* generously over the last century, the decision itself and subsequent Supreme Court cases place real limits on coercive medical interventions. In 1905, Justice Harlan made clear that unreasonable, arbitrary or oppressive vaccination mandates could violate the Fourteenth Amendment Due Process and Equal Protection Clauses. He foresaw that mandates “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.”³⁰²

The parents in this hypothetical argue that the hepatitis B mandate for preschoolers is precisely such an abuse of the police power, going far beyond what is reasonably required for the safety of the public. Later cases have widened the scope of personal autonomy in medical decision-making. As Justice Stevens warned in his *Washington v. Harper* dissent, a state’s “abstract, undifferentiated interest in the preservation of life may in fact overwhelm real individuals’ best interests.”

The hepatitis B vaccination mandate—not primarily for the benefit of young children, and inadequately tested for their safety—has failed to honor young children’s liberty, equal protection, and health. On the CDC’s record, there was no clear medical rationale for introducing the vaccine for young children. The apparent explanation for the dramatic turnaround in federal vaccination recommendation was financial, not medical.

Professor Shapiro raises many important and interesting points in his response, but his expansive analysis seems to bypass the precise reasons he finds the hepatitis B vaccination mandate necessary for children under age six. What is the basis, according to his constitutional logic, for compelling these children, who are presumably not sexually active, drug using, or at risk of other routes of infection, during early childhood? What important governmental objectives does the mandate serve when these children’s artificial immunity will wane or be nonexistent by the time they are potentially at risk of sexual or IV drug infection? What distinguishes a hepatitis B mandate for preschoolers from the “spectacle of unneeded coercion” that Professor Shapiro warns against?

In concluding, Professor Shapiro suggests that readers comply with vaccination recommendations but be alert to potential conflicts of interest. But this conclusion implies that readers get to make up their own minds—just what the parents of preschoolers in forty-seven states do not get to do for the hepatitis B vaccine.

Justice Jackson wrote in his concurrence in *Skinner*, “There are limits to the

302. *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905) (citing *Wis., Minn. & Pac. R.R. v. Jacobson*, 179 U.S. 287 (1900)).

extent to which a legislatively represented majority may conduct biological experiments at the expense of . . . a minority”³⁰³ It is time to reconsider hepatitis B vaccination mandates for preschool children. If federal agencies, advisory bodies, and state legislatures will not do so, then, as Justice Harlan wrote in *Jacobson*, it may be time for “the courts to interfere for the protection of such persons.”³⁰⁴

303. *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 546 (1942) (Jackson, J., concurring).

³⁰⁴*Jacobson*, 197 U.S. at 28.