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Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?

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VANISHING VACCINATIONS: WHY ARE SO MANY AMERICANS OPTING OUT OF VACCINATING THEIR CHILDREN?

Steve P. Calandrillo*

Vaccinations against life-threatening diseases are one of the greatest public health achievements in history. Literally millions of premature deaths have been prevented, and countless more children have been saved from disfiguring illness. While vaccinations carry unavoidable risks, the medical, social and economic benefits they confer have led all fifty states to enact compulsory childhood vaccination laws to stop the spread of preventable diseases. Today, however, vaccines are becoming a victim of their success—many individuals have never witnessed the debilitating diseases that vaccines protect against, allowing complacency toward immunization requirements to build. Antivaccination sentiment is growing fast in the United States, in large part due to the controversial and hotly disputed link between immunizations and autism. The internet worsens fears regarding vaccination safety, as at least a dozen websites publish alarming information about the risks of vaccines. Increasing numbers of parents are refusing immunizations for their children and seeking legally sanctioned exemptions instead, apparently fearing vaccines more than the underlying diseases that they protect against. A variety of factors are at play: religious and philosophical beliefs, freedom and individualism, misinformation about risk, and overperception of risk.

State legislatures and health departments now face a difficult challenge: respecting individual rights and freedoms while also safeguarding the public welfare. Nearly all states allow vaccination exemptions for religious reasons and a growing number provide “philosophical” opt-outs as well. However, in all but a handful of jurisdictions, neither objection is seriously documented or verified. Often, the law requires a parent to do no more than simply check a box indicating she does not wish her child to receive immunizations. The problem is exacerbated by financial incentives schools have to encourage students to opt out of vaccinations. The rise in parents opting out has caused the AMA grave concern, with many experts decrying the rise of so-called “exemptions of convenience.” In some areas, nearly one out of five children have not received their recommended vaccines. The consequences are serious not only for those unprotected children, but for the rest of society as well. “Herd immunity” is threatened as more and more parents free ride off of the community’s dwindling immunity, and outbreaks of diseases thought to have been conquered have already occurred. Lawsuits against vaccine manufacturers threaten

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them with bankruptcy, costs are being externalized onto the healthcare and legal systems, and vulnerable populations are suffering harm or even death. In the interests of social welfare, state legislatures and health departments should consider methods to ensure that the exemption process is carefully tailored to prevent check-the-box opt-outs of convenience, while still allowing exemptions for those with earnest and informed convictions or medical reasons.

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INTRODUCTION

The headline screamed, “Measles Blamed in 42 Deaths; Epidemic Expected to Top 16,000 by Year’s End.”¹ Another ominously warned, “Measles Spreading: Polio, Diphtheria Next?”² The year and the place? One might reasonably guess the turn of the 19th century in any number of undeveloped nations. Sadly and shockingly, the year was 1990, and the country was the United States.

This tale is not unique. In addition to the 55,000 American measles cases and 130 deaths between 1989 and 1991,³ the disease afflicted 125 others in a Christian Science School in Illinois in 1985.⁴ Outbreaks among the Amish occurred again in 1987 and 1988, killing two.⁵ Rubella, a supposedly “nothing disease,” attacked 890 children in Amish areas in 1991, leading to more than a dozen permanently deformed children.⁶ America’s last two polio

1. See Steve Sternberg, *Measles Blamed in 42 Deaths; Epidemic Expected to Top 16,000 by Year’s End*, ATLANTA J. CONST., Dec. 26, 1989, at B4. See also Coroner Faults State in Measles Deaths: Warning Signs Were There, He Says, ORANGE COUNTY REGISTER, Mar. 31, 1990, at A3 (noting that 33 deaths in California alone could have been prevented had citizens been vaccinated); Robert Byrd, *More Measles Cases, Deaths Blamed on Failure to Vaccinate*, BATON ROUGE MORNING ADVOCATE, May 29, 1991, at 11A; Steve Sternberg, *Measles Cases Climb by 25%: 64 Deaths Reported in 22,700 Cases in this Year’s Epidemic*, ATLANTA J. CONST., Oct. 18, 1990, at A6.

2. See Irene Wielawski, *Measles Spreading: Polio, Diphtheria Next?*, L.A. TIMES, July 29, 1990.

3. See WASHINGTON STATE DEP’T OF HEALTH, CHILDHOOD IMMUNIZATIONS, available at <http://www.doh.wa.gov/cfh/immunize/childhood.htm> [hereinafter WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS] (on file with the University of Michigan Journal of Law Reform).

4. See Donald G. McNeil, Jr., *Worship Optional: Joining a Church to Avoid Vaccines*, N.Y. TIMES, Jan. 14, 2003, at F1, F4 [hereinafter McNeil, *Worship Optional*]. Of the 125 cases documented in the Illinois Christian Science school in 1985, three lives were lost. See also *Measles Linked to 3 Deaths at Christian Scientist School*, HOUS. CHRON., Mar. 5, 1985, at 4.

5. See McNeil, *Worship Optional*, supra note 4, at F4.

6. See Donald G. McNeil, Jr., *When Parents Say No to Child Vaccinations*, N.Y. TIMES, Nov. 30, 2002, at A1, A12 [hereinafter McNeil, *When Parents Say No*]. Dr. Edward Rothstein opined

outbreaks occurred among Amish and Mennonite communities and in a Christian Science school in Connecticut.⁷ All could have been avoided if the parents of the children afflicted had not opted out of vaccination.

Sadly, these tragedies may be more likely to occur today than ten or twenty years ago. On Vashon Island, Washington, nearly one in five schoolchildren opted out of immunizations in the year 2000, as some residents prefer alternative therapies and homeopathy to vaccines.⁸ Unfortunately, outbreaks of whooping cough—which can be fatal in infants—struck the island every year between 1995 and 1999, hospitalizing some babies and leaving other children with chronic asthma.⁹ Yet, one resident interviewed still “consider[ed] well-baby care to be a capitalist plot,” and prefers not to immunize her children to this day despite having been a victim of tetanus herself since she too was never vaccinated as an infant.¹⁰

The law faces a difficult challenge in responding to situations like these: namely, how to balance public health welfare with a parent’s individual right and freedom to raise her child as she sees fit. While “compulsory” vaccination laws in all states require immunizations prior to school entry, they are in fact not usually mandatory. Exemptions to vaccination requirements are often easy

that rubella “is, for the most part, a nothing disease”—but the reason to keep vaccinating against it is to protect unborn fetuses. *Id.* at A12.

7. See McNeil, *Worship Optional*, *supra* note 4, at D4. The Amish and Mennonite polio outbreaks occurred in 1979; the Christian Science school experienced theirs in 1972. *Id.* Fortunately, polio is one of few diseases listed as completely eliminated inside the United States today. However, the rest of the world cannot make the same claim, and any unvaccinated child is a mere airplane ride away from potential exposure.

8. See McNeil, *When Parents Say No*, *supra* note 6. In 2000, 18% percent of Vashon Island’s 1,600 elementary school students were granted legal exemptions from vaccinations (this does not necessarily mean that those children received *no* vaccinations; merely that they did not receive *some* immunizations). When contacted about this number, Vashon Island’s Chamber of Commerce responded that the figures represented just one year, and that a much lower percentage of the total population remains unvaccinated. E-mail from Susan Darr, Office Manager, Vashon Island Chamber of Commerce, to Steve P. Calandrillo, Associate Professor of Law, University of Washington School of Law (June 2, 2003 1:19 PM) (on file with the University of Michigan Journal of Law Reform). However, Vashon Island’s school nurse Kate Packard said recently that “Vashon’s high rate of exemptions has not changed since the New York Times (story).” Kate Packard, Letter to the Editor, VASHON BEACHCOMBER, Feb. 12, 2003. Further, 1999 produced a pertussis epidemic on the island with 48 confirmed cases, a rate of disease 20 times higher than neighboring King County. *Id.*

9. See McNeil, *When Parents Say No*, *supra* note 6. Whooping cough continues to afflict the greater King County, Washington area, as Seattle Public Health authorities issued an alert this summer concerning the alarming number of new cases. See *Whooping Cough Cases Spike in King County*, KIROTV.COM, available at <http://www.kirotv.com/health/2303547/detail.html> (on file with the University of Michigan Journal of Law Reform).

10. See McNeil, *When Parents Say No*, *supra* note 6, at A12. Another resident was sorry she let the hospital give her daughter vaccines, stating it was a “moment of weakness.” *Id.*

to receive—in some states, one must merely check a box to legally opt out.¹¹ Alternatively, if documentation is required, one is welcome to join the Congregation of Universal Wisdom, whose tenets hold that “Universal Wisdom is the Supreme Master of all levels in creation” and that the “laying on of hands to the vertebrae shall be the sole means of maintaining the life force.”¹² Further, “[n]o member of the Congregation shall have injected . . . into the body any foreign materials of unhealthy or unnatural composition [i.e., vaccines].”¹³ The Congregation is growing fast—to date, it claims over 5,000 members in 28 states, primarily parents who are seeking exemptions to vaccination requirements.¹⁴

So far the United States has been extremely lucky: most outbreaks of preventable disease in recent years have been confined to dozens or hundreds of people (excluding the 55,000 victims of measles between 1989 and 1991¹⁵). Measles, mumps, polio, diphtheria and other now easily preventable diseases no longer cause mass deaths in America, although the rest of the world is not nearly as fortunate.¹⁶ Consequently, media coverage has largely passed over this lurking danger in America, often giving greater coverage to the risks posed by vaccines or the controversial link between immunizations and autism. Today, however, with exemption rates pushing higher and the new omnipresent threat of

11. See, e.g., WASHINGTON STATE DEP'T OF HEALTH, CERTIFICATE OF IMMUNIZATION STATUS, (DOH Form 348-D13(X), Feb. 1999) (including a “Statement of Exemption to Immunization Law” which requires only that a parent check a box for either a “personal” or “religious” exemption) (attached as Exhibit A).

12. See McNeil, *Worship Optional*, *supra* note 4, at F1. Dr. Walter P. Schilling is the leader of the Congregation of Universal Wisdom, and proudly boasts that he regards Western medicine as paganism or Satanism. His church now claims 5,520 members in 28 states, and is composed primarily of families seeking vaccination exemptions. *Id.*

13. *Id.*

14. See *id.*

15. See WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS, *supra* note 3.

16. Diphtheria remains a deadly force in the former Soviet Union countries. See IMMUNIZATION ACTION COALITION, WHAT IF YOU DON'T IMMUNIZE YOUR CHILD, available at <http://www.immunize.org/catg.d/p4017.pdf> (on file with the University of Michigan Journal of Law Reform). Whooping cough has claimed thousands of victims in Japan and England. See E.J. Gangarosa et al., *Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story*, 351 LANCET 356 (1998) (finding that in eight countries where immunization coverage was reduced, the rate of pertussis surged 10 to 100 times compared to the rate in countries where vaccinations were continued). Measles continues to wreak utter havoc globally, causing 30 million cases annually, and approximately 900,000 deaths. See CENTERS FOR DISEASE CONTROL NATIONAL IMMUNIZATION PROGRAM, WHAT WOULD HAPPEN IF WE STOPPED VACCINATIONS, available at <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm> [hereinafter CDC, IF WE STOPPED VACCINATIONS] (on file with the University of Michigan Journal of Law Reform).

bioterrorism,¹⁷ this threat to public health cannot be ignored any longer.

Part I of this Article details the historical development and medical achievements made possible by vaccines. From Edward Jenner to Jonas Salk to Albert Sabin, immense strides have been made in eradicating or substantially eliminating some of the worst diseases in human history. Smallpox, polio, measles, mumps, rubella, diphtheria, pertussis, tetanus, influenza, hepatitis A and B, and even the chicken pox are all now largely preventable.¹⁸ Literally hundreds of millions of deaths have been avoided and many more lives markedly improved, to say nothing of the financial ramifications for the American healthcare system. All fifty states have therefore enacted compulsory childhood vaccination laws to keep immunization rates high. The Supreme Court has reinforced the government's police power to require vaccinations in the name of overall public safety, holding that important individual liberty rights (to opt out from vaccines) do not override other people's rights (to communal health safety).¹⁹ Subsequent cases have confirmed that compulsory vaccination laws do not violate one's constitutional right to Due Process or Equal Protection, or interfere with the practice of religion under the First Amendment.²⁰

17. Experts fear that countries like Russia may be capable of using the smallpox virus as a biological warfare agent. See MARY-JANE SCHNEIDER, INTRODUCTION TO PUBLIC HEALTH 137, 158 (2000). If this nightmare ever became reality, literally hundreds of millions of unvaccinated individuals across the world would perish. See also Jon Cohen & Eliot Marshall, *Vaccines for Biodefense: A System in Distress*, 294 SCI. 498 (2001) (describing the threat that terrorist attacks present and highlighting the fact that bioterrorism vaccine development has lagged due to lack of commercial interest and management snafus). Given this potential threat, Maxine Hayes adds that a well-vaccinated population should be considered part of our national security efforts. E-mail from Maxine Hayes, Health Officer, Washington State Dep't of Health, to Steve P. Calandrillo, Associate Professor of Law, University of Washington School of Law (July 25, 2003, 10:16 AM) (on file with the University of Michigan Journal of Law Reform).

18. See VACCINE EDUCATION CENTER AT THE CHILDREN'S HOSPITAL OF PHILADELPHIA, THE FACTS ABOUT CHILDHOOD VACCINES, Jan. 2003 [hereinafter VACCINE EDUCATION CENTER]. Vaccines for other viruses and diseases are also available, including anthrax, rabies, cholera, plague, Lyme disease, typhoid, and yellow fever. See *Impact of Vaccines Universally Recommended for Children—United States, 1990–1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 243, tbl. 1 (1999), available at <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00056803.htm> [hereinafter *Impact of Vaccines*] (on file with the University of Michigan Journal of Law Reform).

19. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25–27 (1905) (holding that the City of Cambridge had the right to require that all citizens receive a smallpox vaccination, provided certain protections for the individual are accommodated consistent with liberty principles under the Due Process Clause).

20. See *Prince v. Massachusetts*, 321 U.S. 158, 167–70 (1944) (holding that the First Amendment's Free Exercise Clause does not allow for the right to expose the community or one's children to harm from disease); *Adams v. Milwaukee*, 228 U.S. 572, 581–82 (1913)

Part II analyzes the reasons for the growing antivaccination sentiment in America. Vaccines have become a victim of their tremendous success—as horrific diseases like smallpox and polio have all but disappeared in America, today’s generation no longer fears them as our grandparents did, allowing complacency towards immunization requirements to build.²¹ Vaccines do pose health risks—most minor but some serious—that lead parents to have cause for concern. Immunization opponents also raise deeply held beliefs in individualism and freedom from government regulation and medical intervention as justifications for their decision to opt out. The internet fuels this opposition, with dozens of websites spreading information and sometimes misinformation about vaccine safety.²² Additionally, well-meaning parents may overperceive the true risks that exist, influenced by widespread media coverage of the highly controversial link between vaccines and autism.²³ All

(holding that vaccination regulations treating cows held outside the city differently than those held inside the city do not violate Fourteenth Amendment; they are not discriminatory because they have “a proper relation to the purpose to be accomplished”); *Wright v. DeWitt Sch. Dist.*, 385 S.W.2d 644, 648–49 (Ark. 1965) (holding that a compulsory vaccination law with no religious exemption is constitutional because the right of free exercise is subject to reasonable regulation for the good of the community as a whole); *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951) (holding that school vaccination requirements do not deprive individuals of liberty and property interests without due process of the law); *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979) (allowing religious exemption to vaccination violates Equal Protection Clause because it “discriminates against the great majority of children whose parents have no such religious convictions”). Other cases have upheld exemptions for religious and philosophical reasons. *See, e.g.*, *Bowden v. Iona Grammar Sch.*, 726 N.Y.S.2d 685, 686–87 (N.Y. App. Div. 2001) (holding that parents who followed practices of “Temple of the Healing Spirit” were entitled to religious exemption); *In re LePage*, 18 P.3d 1177, 1180 (Wyo. 2001) (holding that Department of Health cannot inquire into sincerity of mother’s religious beliefs). No case, however, holds that these exemptions must be provided by states. In fact, two states (Mississippi and West Virginia) allow no religious exemptions at all. *See infra* note 26.

21. *See* McNeil, *When Parents Say No*, *supra* note 6, at A12.

22. *See* Robert M. Wolfe et. al, *Content and Design Attributes of Antivaccination Websites*, 287 J. Am. Med. Ass’n 3245 (2002). *See also* MERCOLA.COM website, *How to Legally Avoid Unwanted Immunizations of All Kinds*, available at http://www.mercola.com/article/vaccines/legally_avoid_shots.htm (stating that “nobody, anywhere or any time and under any circumstances has the right or power in this country to immunize you or your children against your will and conviction”) (on file with the University of Michigan Journal of Law Reform); CITIZENS FOR HEALTHCARE FREEDOM website, available at <http://www.citizensforhealthcarefreedom.org>; NATIONAL VACCINE INFORMATION CENTER website, available at <http://www.909shot.com/> (“Vaccinations shouldn’t hurt a child but sometimes they do. Before your child takes the risk, find out what it is.”) (on file with the University of Michigan Journal of Law Reform).

23. *See, e.g.*, Maggie Fox, *Vaccine-Autism Connection? Congressman Urges Investigation*, REUTERS, Apr. 7, 2000, available at http://www.yourlawyer.com/practice/news.htm?story_id=51&topic=Thimerosal (on file with the University of Michigan Journal of Law Reform); *60 Minutes: MMR Vaccine* (CBS television broadcast, Nov. 12, 2000).

of these factors combine to spur lawsuits against vaccine manufacturers, producing upward pressure on prices and vaccine shortages as makers leave the market.²⁴ Congress responded to some of these concerns in the mid-1980s with the National Childhood Vaccine Injury Act, which limited liability of producers and set compensation rates for Americans who are legitimately harmed by the inevitable side effects of vaccines.²⁵ Still, no action has stemmed the tide of legally sanctioned exemptions to vaccination requirements, or the implications that a parent's decision to opt out presents for her child.

Today, 48 states provide for religious exemptions to compulsory vaccination laws.²⁶ Increasingly, states are also permitting "philosophical" beliefs to serve as a justification for a parent's decision to avoid immunizing her child.²⁷ Critics contend that these opt-outs sometimes lead to "exemptions of convenience," as parents without any real reason for objecting to vaccination policy may simply check a box "opting out" rather than be troubled to undertake the effort to complete their child's immunization schedule before he or she enrolls in school.²⁸ Worse, federal and state governments unintentionally give schools financial incentives to encourage their students to opt out of vaccinations.²⁹ Often, full funding cannot be received until the school demonstrates that a child has been completely vaccinated, or that she has legally opted out.³⁰ When

24. See Martin Enserink & Richard Stone, *U.S. Vaccine Supply Falls Seriously Short*, 295 SCI. 1998 (2002).

25. See Robert Rabin, *Some Thoughts on the Efficacy of a Mass Toxics Administrative Compensation Scheme*, 52 MD. L. REV. 951, 958–60 (1993) (detailing the "narrowly focused no-fault" compensation scheme of The National Childhood Vaccine Injury Act of 1986).

26. See James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 874 n.233 (2001–02) (noting that only two states, West Virginia and Mississippi, lacked religious exemptions in their compulsory vaccination statutes as of the 1999–2000 school year).

27. See *id.* at 874 n.234.

28. See Bruce Jancin, *Exemptions to Mandatory School Immunization Laws are Climbing*, FAM. PRAC. NEWS, Aug. 15, 2002 (citing Dr. Edward Marcuse, professor of pediatrics at the University of Washington).

29. See Edgar K. Marcuse, Plenary Presentation—Life, Liberty and the Pursuit of Public Health: Reflections on Mandates and Exemptions 110–12, 36th National Immunization Conference Proceedings, Denver, CO (2002). Government funding is generally tied to student enrollment. However, since schools are not granted full funding for students with incomplete immunization records, it can be tempting to encourage those noncompliant students to opt out of vaccines so that funding can be received.

30. Marcuse reasonably believes that the government did not intentionally create this perverse incentive structure. E-mail from Dr. Edgar Marcuse, Professor of Pediatrics at the University of Washington and Associate Medical Director for Quality Improvement at Children's Hospital and Regional Medical Center, to Steve P. Calandrillo, Associate Professor of Law, Univ. of Washington School of Law (July 23, 2003, 3:59 PM) (on file with the University

confronted with students who have incomplete immunization records, it can be very tempting for cash-strapped educators to encourage parents to opt out in order to receive money for their child's books and teachers.

Part III details the repercussions of the rise in exemption rates. "Herd immunity" is threatened as more parents opt out of vaccinating under the rationale that "if everyone else is protected, then so is my child—so why take even the minute risk of any vaccine side effect at all?" Unfortunately, this triggers a classic collective action problem: increasing numbers of free-riders undermine society's ability to achieve a critical mass of people who are vaccinated. The declining community immunity no longer protects members in the group who have not yet been immunized or whose immune systems are more vulnerable due to age or infirmity. Sadly, as exemptions proliferate, disease "hot spots" are cropping up across the United States where large pockets of children have not received many or any of their mandatory immunizations.³¹ The consequences are not merely academic—outbreaks of measles, whooping cough, mumps, rubella and diphtheria are reoccurring, costing hundreds of lives and hospitalizing thousands more.³² Negative externalities are imposed upon well-intending parents, as their young infants may be exposed to life-threatening illnesses before they even have the ability to complete the recommended childhood immunization schedule. Others, often in the elderly segment of the population or those afflicted with HIV or cancer, have weakened immune systems that leave them susceptible despite previous vaccinations. Finally, the rise in exemptions imposes substantial financial burdens on the healthcare system in dealing with the outbreaks that do occur.³³

Part IV takes up the ultimate question of what the law can and should do about this public health issue. Legislators must not sit idly by if exemptions of convenience continue to increase—rather,

of Michigan Journal of Law Reform). Rather, the idea was simply to tie government funding to enrollment. However, since funding is withheld for students with incomplete immunization records, the unintended consequence may be that exemptions to vaccinations are encouraged.

31. See McNeil, *When Parents Say No*, *supra* note 6, at A1. One should be careful to note that nationwide vaccination rates are quite high overall; the proliferation of exemptions, however, causes pockets to arise where immunization coverage is far below national averages.

32. See IMMUNIZATION ACTION COALITION, *supra* note 16 (detailing the consequences from recent outbreaks of whooping cough, measles, diphtheria and chicken pox).

33. See WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS, *supra* note 3 (noting that the 1989–91 measles outbreak in the U.S. caused 44,000 days of hospitalization and resulted in \$100 million in direct medical costs).

the exemption process should be a thoughtful one, not a rubber stamp. The Supreme Court has long laid out the principle that government can regulate for the public safety, though those concerns must be balanced with individual freedom and rights. Given the harm that opting out imposes on innocent parties, the exemption process cannot be trivialized into “checking a box.” Schools should not be given financial incentives to encourage parents to opt out. Rather, careful deliberation must be given and exemptions awarded only where medically necessary or where parents can demonstrate their informed and sincerely held objections. This is a unique problem that the law can actually do something about in order to balance societal health with individual rights.

I. VACCINES: HISTORY, BENEFITS, AND THE LAW

The development of vaccines in the fight against life-threatening disease was a remarkable breakthrough. Infectious diseases were far and away the major killers of human beings until the beginning of the twentieth century.³⁴ Diseases such as smallpox, the bubonic plague, polio, diphtheria, tuberculosis, measles, mumps, and rubella claimed thousands of lives.³⁵ Today, many of these illnesses have been eliminated or dramatically reduced because of groundbreaking vaccinations that immunize individuals against them. Ironically, the magnitude of vaccines’ success has decreased the attention paid toward immunization requirements, for many Americans alive today have never seen the ravages of the diseases that took their ancestors’ lives.³⁶

Vaccination is the medical process by which an agent similar to the disease or virus being prevented is deliberately introduced into a non-exposed individual, thereby causing the body to produce antibodies against the underlying illness.³⁷ The ultimate goal is that

34. See *Impact of Vaccines*, *supra* note 18.

35. See *id.*; see also Editorial, *Death Throes of a Crippler*, N.Y. TIMES, May 27, 2003 at A24 (noting that the world has been spared 40 million smallpox deaths since its eradication in 1977, and that eliminating polio from the face of the earth would bring similarly monumental benefits as well).

36. See Kathryn M. Edwards, Editorial, *State Mandates and Childhood Immunization*, 284 J. AM. MED. ASS’N 3171 (2000) (noting that vaccines are under pressure today because diseases they prevent are rare and many parents have never seen or heard of them).

37. See Hodge & Gostin, *supra* note 26, at 837 n.19. The terms “vaccination” and “immunization” are often used interchangeably, though immunization is the more inclusive term. It denotes the process of inducing or providing immunity artificially by administering an immunobiologic agent, and can be either “active” or “passive.” *Id.* Passive immunization

the attenuated or killed microorganisms (or derivative antigen) in the vaccine will create immunity by artificial means—thereby protecting the individual against the underlying disease without forcing her to endure the daunting task of surviving it first.³⁸

A. Historical Development of Vaccinations

The historical origin of vaccination as a means to control the spread of disease traces its roots as far back as the first millennium in various cultures and countries.³⁹ Smallpox, a disease which shares few peers when it comes to population devastation,⁴⁰ had claimed millions of lives throughout Asia, the Roman Empire, Europe and the Americas.⁴¹ To combat this highly contagious, disfiguring and often deadly illness, extreme measures were taken. Sometime before 1000 A.D., it became the practice in India to deliberately expose patients to the smallpox virus itself (as opposed to a weakened or inactivated related agent) in order to create immunity where there once was none.⁴² This process, known as variolation,⁴³ sought the intentional transmission of a mild form of the disease, with the intended result that the illness be less severe than one acquired naturally.⁴⁴ Because second attacks of smallpox after variolation were rare, it was assumed (correctly) that getting it once—and surviving it—would lead to immunity.⁴⁵ However, those

involves the administration of antibodies produced by an immune animal or human, and provides short-term protection against infection. In active immunization (i.e., vaccination), the vaccine induces the host's own immune system to provide protection against the pathogen. *Id.* (citing W. Michael McDonnell & Frederick K. Askari, *Immunization*, 278 J. AM. MED. ASS'N 2000 (1997)).

38. See J. Alastair Dudgeon et al., *Principles in the Development and Use of Immunization Products*, in *IMMUNIZATION: PRINCIPLES AND PRACTICE* 40 (J. Alastair Dudgeon & William A.M. Cutting eds., 1991).

39. See Hodge & Gostin, *supra* note 26, at 837.

40. See J. Alastair Dudgeon, *Historical Introduction*, in *IMMUNIZATION: PRINCIPLES AND PRACTICE* 2 (J. Alastair Dudgeon & William A.M. Cutting eds., 1991).

41. See SCHNEIDER, *supra* note 17, at 136 (citing L. GARRETT, *THE COMING PLAGUE: NEWLY EMERGING DISEASES IN A WORLD OUT OF BALANCE* 403 (1994)). For example, by the end of the 18th century, an estimated 400,000 people died annually from smallpox in Europe. *Id.*

42. See Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, in *VACCINES* 74 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed., 1999). From India, the practice spread to China, western Asia, Africa and eventually to Europe and North America. *See id.*

43. See Dudgeon, *supra* note 40, at 2.

44. See Henderson & Moss, *supra* note 42, at 74–75.

45. See Dudgeon, *supra* note 40, at 3.

infected through variolation could still transmit smallpox to others and many suffered terrible deaths in the process.⁴⁶

Centuries later, Dr. Edward Jenner, a medical pioneer often referred to as the “Father of Vaccination,” developed a safer and more effective alternative to variolation to combat smallpox.⁴⁷ Jenner’s first “vaccination,” as it came to be called, occurred in 1796, when he took cowpox matter from the arm of a dairymaid who had previously had the cowpox disease.⁴⁸ He transmitted this virus into a healthy eight-year-old boy, who subsequently became immune to the related smallpox disease.⁴⁹ The impact of Jenner’s contribution cannot be overstated, as he was the first to recognize the practical significance of the relationship between cowpox and smallpox, and use vaccination (with a weaker and related virus) rather than variolation to induce immunity.⁵⁰

Shortly after Jenner published his groundbreaking results in 1798, his work was translated into six languages, and within a decade the smallpox vaccine was transported to countries throughout the world.⁵¹ By the early 1800s, many European nations began compulsory vaccination programs of their citizenry, or at least witnessed widespread utilization of vaccines by members of the upper class.⁵² In 1840, the English Parliament enacted a bill recommending vaccination and prohibiting variolation.⁵³ In 1853, England and Wales promulgated statutes requiring all individuals to be vaccinated against smallpox,⁵⁴ and over the next 40 years, the English Parliament passed multiple laws making additional vaccinations compulsory.⁵⁵ Compulsory vaccination in England ended in 1946,⁵⁶ but reappears as outbreaks of disease occur.⁵⁷

46. See Henderson & Moss, *supra* note 42, at 74–75.

47. See Dudgeon, *supra* note 40, at 5. Jenner is credited with creating the science of immunology, as he was the first physician to use a systematic, deliberate inoculation to induce immunity based on medical principles. See Susan L. Plotkin & Stanley A. Plotkin, *A Short History of Vaccination*, in *VACCINES 1* (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999). See also Hodge & Gostin, *supra* note 26, at 840.

48. Interestingly, the etymology of the word “vaccination” is derived from the Latin word “vacca,” which means cow. See Dudgeon, *supra* note 40, at 6. Today, the smallpox vaccine contains the vaccinia virus.

49. See Hodge & Gostin, *supra* note 26, at 838–40.

50. See Dudgeon, *supra* note 40, at 7–8.

51. See Henderson & Moss, *supra* note 42, at 75.

52. See Hodge & Gostin, *supra* note 26, at 840–41.

53. See Dudgeon, *supra* note 40, at 9.

54. See Dudgeon et al., *supra* note 38, at 59.

55. See Dudgeon, *supra* note 40, at 9.

56. See *id.*

57. Since 1946, all forms of immunization in the United Kingdom are voluntary and require informed consent. See Dudgeon et al., *supra* note 38, at 60.

The United States also began to realize the benefits of vaccinations in the 1800s, though full-scale national immunization efforts would have to wait another century. President Thomas Jefferson was the first to recognize the public health value of vaccinations.⁵⁸ Jefferson, occasionally called “the greatest patron of vaccination in America,”⁵⁹ inoculated hundreds of his own family members and friends, directing vaccination programs in the south and developing safer methods for vaccine transportation.⁶⁰ In 1809, Massachusetts became the first state to make vaccination against smallpox mandatory.⁶¹ By the mid to late 1800s, other states, especially in the Northeast and Midwest, had passed their own smallpox vaccination requirements.⁶²

The science of immunology quickly progressed through the end of the 19th century and into the first part of the 20th century with breathtaking results. A new chapter in the history of vaccinations opened when killed agents were utilized instead of live, attenuated vaccines.⁶³ These inactivated products promised similar immunogenic effect, but with markedly improved safety. Louis Pasteur and Robert Koch were particularly influential in this period, as their research built on Jenner’s discoveries and eventually led to vaccines for cholera and anthrax.⁶⁴

By 1949, smallpox vaccination had enjoyed such dramatic success that the World Health Organization (WHO) identified the dreaded disease as an illness capable of complete eradication.⁶⁵ Officials embarked upon an expansive public health program involving “ring vaccination” of everyone within the vicinity of a smallpox case.⁶⁶ After sustained and dedicated efforts, the WHO

58. See Hodge & Gostin, *supra* note 26, at 842–43.

59. See *id.*

60. See *id.* Jefferson was influenced by Dr. Benjamin Waterhouse, who engaged in his own vaccination experiments in the United States with knowledge of Jenner’s findings and advocated strongly and passionately for the widespread use of vaccination to exterminate smallpox.

61. See Dudgeon et al., *supra* note 38, at 59.

62. See John Duffy, *School Vaccination: The Precursor to School Medical Inspection*, 33 J. HIST. MED. 344, 349–51 (1978). See also HARVEY CORTLANDT VOORHEES, *THE LAW OF THE PUBLIC SCHOOL SYSTEM* 15–19 (1916).

63. See Dudgeon, *supra* note 40, at 12.

64. See Plotkin & Plotkin, *supra* note 47, at 2–3; Dudgeon, *supra* note 40, at 8–13.

65. See Dudgeon, *supra* note 40, at 22.

66. See *id.* at 22–23. Experts estimated that vaccination of about 80% of the world’s population would be adequate to bring the disease under control. However, mass vaccination failed to succeed in many tropical countries, leading to new strategies in the fight against the disease. A reward system for reporting cases was promoted by mass media, especially over the radio. Identification of victims was followed by strict ring vaccination of

reported in 1980 that the planet was free of smallpox,⁶⁷ making it the first epidemic disease to be completely eliminated from the face of the earth.⁶⁸

While the defeat of smallpox is proclaimed as one of the greatest victories in the history of human healthcare,⁶⁹ medical science had just scratched the surface of the public welfare achievements made possible by vaccination. A vaccine against polio—a devastating virus which paralyzed or killed over 20,000 Americans per year⁷⁰—was developed to tremendous fanfare in the 1950s by Dr. Jonas Salk. By applying the findings of numerous scientists, Salk discovered a way to produce large quantities of the virus; from others, a method to kill the virus with formaldehyde so that it remained intact enough to cause an antibody response in humans without infecting them as

everyone who came into contact with that person. The method was successful, particularly in countries with scattered populations and rugged terrain. *See id.*

67. *See* WORLD HEALTH ORGANIZATION, *The Global Eradication of Smallpox: Final Report of the Global Commission for the Certification of Smallpox Eradication*, in HISTORY OF INTERNATIONAL PUBLIC HEALTH NO. 4 (1980). *See also* Dudgeon, *supra* note 40, at 22. Today, the smallpox virus officially remains only in laboratories at the Centers for Disease Control and Prevention and in a laboratory in Russia. However, other countries, such as Iraq, have been suspected of maintaining and using the smallpox virus as a biological warfare agent. *See* SCHNEIDER, *supra* note 17, at 137, 158 (citing E. Marshall, *Bioterror Defense Initiative Injects Shot of Cash*, 283 SCI. 1234 (1999); D.A. Henderson, *The Looming Threat of Bioterrorism*, 283 SCI. 1279 (1999)). The threat of smallpox reintroduction into the world is particularly treacherous because it is extremely contagious, highly lethal, has no known cure, and virtually everyone in the world is susceptible to it because immunizations have not been given for over twenty years. *See id.* at 159. As a result of this threat, new efforts have been made to distribute vaccines—starting with President Bush’s plan to vaccinate thousands of “first responders.” *See, e.g.*, Richard Perez-Pena, *Voting for Bush, Voting to Get a Smallpox Shot*, N.Y. TIMES, May 18, 2003, at D2 (describing the current smallpox vaccination effort and noting that it has encountered significant resistance). The resistance is attributable to a number of factors: lack of a perceived threat, lack of enforcement within each state, and fear of adverse effects from the vaccine itself.

68. It is important to keep in mind that any disease (viral or otherwise) that can exist outside of a human host will never be totally eradicated in the true sense of the word. Smallpox is uniquely human and represents a special case in that regard. *See generally* Denise Grady & Lawrence K. Altman, *Beyond Cule: Exotic Pets Come Bearing Exotic Germs*, N.Y. TIMES, June 17, 2003, at D1, D6 (explaining that pox viruses that cross species may be the most enduring diseases, while noting that smallpox has only one natural host, i.e., humans, making eradication possible). Many other viruses, however, are found in animals as well as people. *Id.* Since it is not practical to immunize or eliminate such diseases in the animal population, those diseases will never be totally eradicated in the human population. Hence, vaccination may still be warranted even if no human beings report cases in a given year.

69. *See* SCHNEIDER, *supra* note 17, at 136.

70. *See* Polio Vaccine Information Statement, 42 U.S.C. § 300aa-26 (2000). Since the turn of the 20th century, polio outbreaks had grown more frequent and more devastating. In 1952, some estimates recorded 21,269 cases, making it the worst year on record. *See* Gina Mootrey et al., *Surveillance for Adverse Events Following Vaccination*, in VACCINE PREVENTABLE DISEASE SURVEILLANCE MANUAL 18–12 (1999). Understandably, Salk’s breakthrough was heralded as a landmark achievement at the time.

well.⁷¹ At first, Salk inoculated volunteers, including himself, his wife, and their three sons, with a polio vaccine made from this killed virus.⁷² All who received the test vaccine began producing antibodies to the disease, yet no one became ill. Nationwide testing confirmed the vaccine's safety and efficaciousness, and soon mass vaccination of U.S. schoolchildren was underway.⁷³

A rival researcher, Albert Sabin, thought that Salk's killed-virus polio vaccine was not strong enough for maximum effectiveness.⁷⁴ Sabin attempted to mimic the real-life infection as closely as possible, which meant using a weakened form of the live virus. He experimented with more than 9,000 monkeys and 100 chimpanzees before isolating a rare form of the polio virus that would reproduce in the intestinal tract but not in the central nervous system.⁷⁵ In 1957, Sabin initiated human trials of an oral vaccine that people could swallow rather than receiving via injection. Though his version was initially branded as a "communist vaccine" because it was tested in the Soviet Union,⁷⁶ it was licensed in 1962 and quickly became the immunization of choice until the turn of the 21st century.⁷⁷ The results of Salk and Sabin's innovations were dramatic—within a few decades, polio went from being the most feared disease in America to one which was nearly eliminated, though it continues to inflict paralysis, pain, suffering and death in other parts of the world today.⁷⁸ More importantly, the impact of these two great scientists and their different visions of vaccination

71. While Salk had applied the findings of others in a bid to prevent disease, the success of his vaccination effort won him unsought fame. The March of Dimes, hoping to boost publicity and donations for vaccination programs, lionized Salk to the point of offending his colleagues. Fellow researchers grumbled that Salk had not discovered anything new; but rather had simply applied what already existed. Nevertheless, the timing of Salk's vaccine at the peak of polio's devastation blinded the public to the work of others. See *People and Discoveries: Jonas Salk*, available at <http://www.pbs.org/wgbh/aso/databank/entries/bmsalk.html> (on file with the University of Michigan Journal of Law Reform).

72. See *id.*

73. The massive immunization program was directed by Thomas Francis, Jr., Salk's former mentor. See *id.*

74. See *People and Discoveries: Salk Produces Polio Vaccine*, available at <http://www.pbs.org/wgbh/aso/databank/entries/dm52sa.html> (on file with the University of Michigan Journal of Law Reform).

75. See *id.*

76. See *id.*

77. See Frederick C. Robbins, *The History of Polio Vaccine Development*, in *VACCINES* 18 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed., 1999).

78. See Karen Allen, *India Tackles Child Polio*, BBC NEWS, Feb. 9, 2003, available at <http://news.bbc.co.uk/2/hi/health/2741767.stm> (on file with the University of Michigan Journal of Law Reform).

had a monumental effect on public awareness of immunization in America and the welfare goals it could achieve.⁷⁹

The quest to prevent disease is a never ending one, however. New and improved vaccines have been developed at an unprecedented rate in the last few decades,⁸⁰ and the trend continues to the present day.⁸¹ Scientists are diligently at work on developing vaccines for diseases such as HIV and Alzheimer's.⁸² A vaccine for the new and deadly SARS contagion is being pursued,⁸³ and another might provide the cure for seasonal allergies.⁸⁴ The law must keep pace with scientific developments—and immunization exemptions must not undermine the benefits of vaccinations in the future.

79. Polio cases are now practically unheard of, and ironically are almost always caused by the Sabin vaccine itself—being live, the virus can mutate to a stronger form. Elsewhere, however, there remain thousands of cases of polio per year, mostly in developing nations where vaccination has not become widespread. The World Health Organization has set the goal of worldwide polio eradication by the end of the first decade of the twenty-first century.

80. See *infra* Part I.B.1.

81. Dudgeon et al., *supra* note 38, at 42. See also *Impact of Vaccines*, *supra* note 18 (noting that licensure is anticipated for new vaccines against HIV, influenza, gastric ulcers, cancer caused by *Helicobacter pylori*, cervical cancer, and rheumatic heart disease that results from streptococcal infection).

82. See HIV VACCINES SITE Website, available at <http://www.niaid.nih.gov/daids/vaccine/default.htm>. See also *Team Develops Alzheimer's Vaccine Without Side Effects*, JAPAN TODAY, Apr. 24, 2003, available at <http://www.japantoday.com/e/?content=news&cat=1&id=263352> (on file with the University of Michigan Journal of Law Reform).

83. See Lawrence K. Alman & Denise Grady, *Study of SARS Genome Shows No Big Mutations*, N.Y. TIMES, May 9, 2003, at A13. The 2003 epidemic of Sudden Acute Respiratory Syndrome (SARS) epidemic highlights the unceasing danger of contagious diseases and the need to remain vigilant in their prevention. A SARS vaccine appears possible to create since the virus does not mutate quickly, but development may still take several years.

84. See Suzanne Rostler, *Vaccine May Relieve Seasonal Allergies—Study*, VACCINE-NEWS.COM, Dec. 18, 2001, available at <http://www.vaccinationnews.com/DailyNews/December2001/VaxRelieveSeasAllerg.htm> (on file with the University of Michigan Journal of Law Reform). One problem with new vaccine development, however, is that the pharmaceutical companies which manufacture them must have a large enough market in the end to compensate for the research and development necessary. Thus, the number of people afflicted with an illness can be determinative of whether or not the private financial rewards provide enough incentive for vaccine development. Both SARS and the Ebola virus may suffer from this unfortunate reality, for although these viruses appear susceptible to prevention by vaccination, it is not clear whether or not enough human beings are affected to provide the motivational force for development. In such instances, public officials should call for government involvement and support to spur innovation. For a general discussion of the benefits of government involvement in the creation of drugs or other publicly valuable intellectual property innovations, see Steve P. Calandrillo, *An Economic Analysis of Intellectual Property Rights: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 301 (1998).

B. Benefits of Vaccinations

Vaccines have dramatically reduced morbidity and mortality rates of some of the worst diseases in history by preventing them on the front end. The benefits have been remarkable: millions of deaths have been prevented, millions more lives markedly improved, and billions of dollars of societal resources have been saved for use in countless other valuable endeavors.

1. *Diseases Eliminated*—The science of immunology has improved to the point that today vaccines protect against over twenty deadly diseases, including smallpox, measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), polio, hepatitis A and B, some forms of influenza, pneumococcal disease, *Haemophilus influenzae* type b, and varicella (chicken pox).⁸⁵

A brief overview of today's routinely provided childhood vaccines⁸⁶ and the diseases they prevent follows:

- *Diphtheria, Tetanus and Pertussis ("DTaP") Vaccine*—Diphtheria is an acute infectious disease of the nose and throat, spread from an infected individual when she coughs or sneezes.⁸⁷ A sore throat accompanied by fever and weakness are usually the first symptoms, leading to a thick mucus membrane which covers the entire throat and extends to respiratory passages, making breathing difficult.⁸⁸ Diphtheria can cause paralysis, heart problems, and occasionally death.⁸⁹

85. Since the smallpox vaccine was discovered in 1798, vaccines against dozens of other diseases have been licensed in the U.S.: rabies, typhoid, cholera, plague, diphtheria, pertussis, tetanus, tuberculosis, influenza, yellow fever, poliomyelitis, measles, mumps, rubella, anthrax, meningitis, pneumonia, adenovirus, hepatitis B, *Haemophilus influenzae* type b, Japanese encephalitis, hepatitis A, varicella, Lyme disease, and rotavirus. See *Impact of Vaccines*, *supra* note 18. About half of these are routinely given to all children, while the remainder are used only for selected populations at high risk because of age, medical circumstances or risk behaviors. See CENTERS FOR DISEASE CONTROL, RECOMMENDED CHILDHOOD IMMUNIZATION SCHEDULE—UNITED STATES, 1999, 48 MORBIDITY & MORTALITY WKLY. REP. 12-6 (1999) [hereinafter CDC, IMMUNIZATION SCHEDULE].

86. The recommended childhood vaccination schedule calls for 15-19 separate immunizations against 11 different diseases before the child turns 18 months of age. One might imagine that this is quite a large undertaking given that 11,000 newborns join our world every day in the United States, posing a constant challenge to our vaccine delivery infrastructure. See *Impact of Vaccines*, *supra* note 18 (citing CDC, IMMUNIZATION SCHEDULE, *supra* note 85).

87. See Edward A. Mortimer Jr. & Melinda Wharton, *Diphtheria Toxoid*, in VACCINES 140-42 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

88. See Diphtheria Tetanus & Pertussis Vaccine Information Statement, 42 U.S.C. § 300aa-26 (2001).

89. See Mortimer & Wharton, *supra* note 87, at 140-42.

Tetanus, also known as lockjaw, is a bacterial disease generally transmitted through a cut or puncture wound that becomes contaminated by the tetanus germ.⁹⁰ It is infectious, but not contagious, unlike other vaccine-preventable diseases.⁹¹ The tetanus bacterium releases a potent toxin that poisons nerves and triggers muscle spasms, commonly in the jaw or neck. Breathing and heart problems, as well as death, may also result.⁹²

Pertussis, more commonly referred to as whooping cough, is a highly contagious bacterial respiratory infection spread by coughing or sneezing.⁹³ Beginning symptoms mimic the common cold, but within a few days, coughs come in exhausting bursts, and are followed by a telltale “whooping” sound as the person breathes in.⁹⁴ The long bouts of coughing can make it difficult for children to eat, drink or breathe, and in severe cases, can cause seizures, brain damage and death.⁹⁵

Fortunately, the diphtheria, tetanus and pertussis vaccine (DTaP) protects against these diseases.⁹⁶ Because of the DTaP vaccine, diphtheria is reported only rarely in America today, with only 41 cases documented from 1980 to 1995, and just 2 deaths in the year 2000.⁹⁷ This figure stands in stark contrast to diphtheria’s heyday in the 1800s, when in Massachusetts alone the median death rate from diphtheria was 78 per 100,000 people annually.⁹⁸ In the 1920s, about 14,000 deaths were reported annually,⁹⁹ with the inci-

90. See Steven G.F. Wassilak et al., *Tetanus Toxoid*, in *VACCINES* 441–42 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

91. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16.

92. See *id.*

93. See Kathryn M. Edwards et al., *Pertussis Vaccine*, in *VACCINES* 293–94 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

94. See *id.*

95. See *id.*

96. Note, the DTaP vaccine is a safer version of an older vaccine called “DTP.” The DTP vaccine is no longer used in the United States. See *Diphtheria Tetanus & Pertussis Vaccine Information Statement*, *supra* note 88.

97. See Mortimer & Wharton, *supra* note 87, at 144; *Summary of Notifiable Diseases—United States, 2001*, 50 *MORBIDITY & MORTALITY WKLY. REP.* xii (2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5053a1.htm>. See also Richard Kent Zimmerman et al., *Routine Vaccinations Across the Lifespan, 2003*, 52 *J. FAM. PRAC.* S1, S6 (2003).

98. See Mortimer & Wharton, *supra* note 87, at 144. The death rate of 78 per 100,000 covers the period between 1860 and 1897.

99. See Zimmerman et al., *supra* note 97, at S6. Diphtheria peaked in the United States in 1921, when 206,000 cases and 15,520 deaths were reported. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16. Even though cases are quite rare in America today, the bacteria continues to be passed among people, and data shows there are high rates of susceptibility among adults. This is especially dangerous since other parts of the world, particularly Russia, do not have diphtheria under control. See *id.*

dence of diphtheria rising to over 100 per 100,000 population nationally.¹⁰⁰ In comparison, diphtheria prevalence has declined to less than .01 Americans per 100,000 today.¹⁰¹ In the former Soviet Union, however, lack of coordinated vaccinations have fueled diphtheria epidemics throughout the 1990s, as 150,000 cases and 5,000 deaths were reported in the last decade.¹⁰²

Tetanus, a much less dire public health threat, nonetheless claimed 601 American victims as recently as 1948.¹⁰³ This number has been reduced to just 34 today,¹⁰⁴ but worldwide tetanus still kills 300,000 newborns and 30,000 birth mothers each year who lack proper vaccination.¹⁰⁵

Pertussis (whooping cough) was and is a far more widespread problem in the United States, affecting 265,000 Americans per year in 1934.¹⁰⁶ Before vaccine development, nearly all children developed whooping cough, producing hundreds of thousands of cases annually and up to 9,000 deaths.¹⁰⁷ Today, whooping cough continues to impact thousands of children per year despite the availability of the DTaP vaccine. In fact, reported cases have been *increasing* since the early 1980s with peaks every three to four years.¹⁰⁸ Between 1997–2000, nearly 30,000 cases of pertussis were reported in the U.S., including 62 deaths.¹⁰⁹ Vashon Island in Washington State has witnessed whooping cough outbreaks every year from 1995 through 1999, and other parts of the state have experienced an increase as well.¹¹⁰

• *Measles, Mumps, Rubella* (“MMR” Vaccine)—Measles is a serious and highly contagious disease that causes a high fever, rash, and cold-like symptoms.¹¹¹ A few days after infection, small white spots

100. See Mortimer & Wharton, *supra* note 87, at 145 fig. 9–1.

101. See *id.* at 145.

102. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

103. See Mootrey et al., *supra* note 70, at 18–12.

104. See *id.*

105. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

106. See Mootrey et al., *supra* note 70, at 18–12.

107. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

108. See *id.*

109. See IMMUNIZATION ACTION COALITION, *supra* note 16.

110. See McNeil, *When Parents Say No*, *supra* note 6, at A12. Pertussis outbreaks are occurring elsewhere in Washington state as well, indicating that Vashon Island’s experience may not be due solely to its low immunization levels. See *Whooping Cough Cases Spike in King County*, *supra* note 9.

111. See Stephen C. Redd et al., *Measles Vaccine*, in VACCINES 223–24 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999). Measles is so infectious that virtually everyone in the United States contracted it prior to the vaccine’s availability. If vaccinations were stopped, an estimated 2.7 million people would die across the world every year. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

appear on the inside of the mouth.¹¹² A rash then develops, beginning on the face and spreading rapidly over the neck, upper arms, chest, and finally to the back, abdomen, thighs, legs and feet.¹¹³ The afflicted individual may suffer from ear infections, pneumonia, seizures, brain damage and death.¹¹⁴ Measles spreads so quickly and easily that a child who has not been immunized will most likely contract it.¹¹⁵

Mumps is caused by a virus which produces painful swelling of the glands just above the jaw.¹¹⁶ It can cause headache, fever and mild respiratory symptoms in young children; after puberty, it can cause swollen testes or ovaries.¹¹⁷ Mumps can lead to hearing loss, meningitis, deafness and even brain damage.¹¹⁸

Rubella, popularly known as the German measles or three-day measles, is sometimes referred to as a “nothing disease” because it seldom poses a major risk to American children.¹¹⁹ However, it does put fetuses in considerable danger—pregnant women who are infected by rubella can miscarry or have babies that suffer from severe birth defects such as blindness, deafness and retardation.¹²⁰ The first signs of the illness are often a rash on the face and neck, which spreads swiftly to the trunk, upper arms, thighs and then hands and feet.

Today, measles, mumps and rubella are all preventable by use of the combination MMR vaccine.¹²¹ Before the vaccine was employed, however, a staggering four million cases of the measles occurred annually in the U.S., with an average of 450 deaths per year.¹²² Mumps was certainly less prevalent, but had nonetheless been a

112. See WASHINGTON STATE DEP'T OF HEALTH, IMMUNIZATION MANUAL FOR SCHOOLS, PRESCHOOLS AND CHILDCARE FACILITIES 2-5 (2002) [hereinafter WASHINGTON DOH, IMMUNIZATION MANUAL].

113. See *id.*

114. See *id.*

115. WASHINGTON STATE DEP'T OF HEALTH, THE FACTS ABOUT CHILDHOOD IMMUNIZATIONS (2002) [hereinafter Washington DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS].

116. See Stanley A. Plotkin & Melinda Wharton, *Mumps Vaccine*, in VACCINES 267-68 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

117. See WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2-5.

118. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

119. See McNeil, *When Parents Say No*, *supra* note 6, at A12 (quoting Dr. Edward P. Rothstein).

120. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

121. The measles vaccine was developed and licensed in 1963, mumps in 1967, and rubella in 1970. The three are now used in combination. See Redd et al., *supra* note 111, at 232.

122. See *id.* at 246. The authors note that while an estimated 4 million cases occurred annually, “only” about 400,000 to 500,000 were actually reported. Average deaths of 450 Americans per year comprise the time period between 1953 and 1963. See also CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

commonly diagnosed cause of aseptic encephalitis in childhood prior to vaccination.¹²³ Rubella had tragically caused 50,000 to 60,000 American babies to be born deaf, blind, retarded or with small heads as recently as the 1960s.¹²⁴

Today, however, widespread measles vaccination in the United States has led to a dramatic decrease in its incidence, complications and mortality rate.¹²⁵ While nearly 900,000 cases were reported in 1941,¹²⁶ that number plummeted to under 1,500 by 1983,¹²⁷ and to a mere 37 last year, representing a reduction of more than 99.99% from pre- to post-vaccine years.¹²⁸ (One should note that such progress has not been without setbacks, as a serious American measles epidemic occurred in 1989–91, infecting 55,000 children and killing 132.¹²⁹) Nevertheless, the decline in the last few years has been so extreme that some health officials have publicly proclaimed that measles may be nearing extinction in the United States and that global eradication is possible.¹³⁰ In addition to the thousands of lives at stake, billions of dollars in saved medical costs can be attributed to the measles vaccine since 1963.¹³¹

123. See Plotkin & Wharton, *supra* note 116, at 268.

124. See McNeil, *When Parents Say No*, *supra* note 6, at A12 (citing Dr. Edward Rothstein, a Pennsylvania pediatrician who helped the American Academy of Pediatrics make immunization recommendations).

125. See Redd et al., *supra* note 111, at 222.

126. See Mootrey et al., *supra* note 70, at 18–12.

127. See SCHNEIDER, *supra* note 17, at 138. In the 1980s the measles vaccine ran into some setbacks. Older children who had been vaccinated earlier in their lives began developing the disease as teenagers. The problem was solved by giving a second primary immunization around age four to six. See *id.* Another more significant problem with the measles vaccine was that too many children were not being vaccinated until they were ready to enter school, which meant they were at an increased risk of developing measles at a young age. Between 1989 and 1991, terrible outbreaks occurred, with over 55,000 children in the United States contracting measles and over 130 dying from it. See WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS, *supra* note 3. Today, the public health system strives to do a better job of getting young children immunized against measles. This effort has been successful, as illustrated by the fact that in 1997 there were only 135 cases of measles in the U.S. and just 37 in 2002. See SCHNEIDER, *supra* note 17, at 138; Charles Ornstein, *U.S. Vaccine Program Nearly Erases Measles*, L.A. TIMES, Jan. 26, 2003, at A1. However, measles outbreaks continue to claim millions of victims outside of the United States. See *infra* Part III.B.

128. See Redd et al., *supra* note 111, at 246.

129. See IMMUNIZATION ACTION COALITION, *supra* note 16.

130. See Ornstein, *supra* note 127 (noting that the potential extinction of measles in the U.S. is being hailed by some officials as a victory akin to the defeat of smallpox and polio). However, millions of cases continued to be documented globally each and every year. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

131. See Redd et al., *supra* note 111, at 246 (citing A.B. Bloch et al., *Health Impact of Measles Vaccination in the United States*, 76 PEDIATRICS 524–32 (1985); E.J. HATZIANDREU ET AL., A COST BENEFIT ANALYSIS OF MEASLES-MUMPS-RUBELLA VACCINE, ARLINGTON VA, BATELLE, FINAL REPORT 1–66 (1994)).

Individuals are not nearly as fortunate outside of the United States, as the lack of widespread measles vaccination leads to a shocking 30 million infected children worldwide annually and 777,000 deaths—over half in Africa alone.¹³² With measles continuing to be so prevalent across the world, Americans must remain especially cognizant that its wrath is only one plane ride away.

Mumps, like measles, has also been virtually eliminated in the United States. Prior to the vaccine, an estimated 212,000 American cases were documented in 1964, and mumps was a major cause of deafness in children.¹³³ Compulsory vaccinations against the disease have led to a precipitous decline in reported cases. In 1968, one year after the licensure of the mumps vaccine, 152,209 children were afflicted; by 1996, just 751 Americans suffered a similar fate.¹³⁴ Moreover, systematic study of compulsory mumps vaccination laws has demonstrated that such public safety regulations are extremely effective.¹³⁵

Likewise, rubella is no longer a major problem in the United States, impacting only 345 people per year today.¹³⁶ In 1964–65 however, before rubella immunizations were routinely implemented, approximately 20,000 infants were born with congenital rubella syndrome (CRS), resulting in 2,100 neonatal deaths and 11,250 miscarriages.¹³⁷ Further, of the 20,000 born with CRS, 11,600 were deaf, 3,580 blind and 1,800 mentally retarded.¹³⁸ Thankfully, rubella is now rare and primarily afflicts adults born in countries that do not have routine vaccination programs or which have instituted them only recently.¹³⁹ While most Americans thus have little

132. See *Mass Vaccination Programs Cut Measles Deaths*, REUTERS, May 22, 2003, available at <http://www.alertnet.org/thenews/newsdesk/N22315083.htm> (on file with the University of Michigan Journal of Law Reform). The World Health Organization estimates that 900,000 measles-related deaths occurred in developing countries in 1999. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16.

133. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16.

134. See Plotkin & Wharton, *supra* note 116, at 271–72. There were just 266 total reported mumps cases in 2001. See *Summary of Notifiable Diseases—United States, 2001*, *supra* note 97.

135. See B.P. Charles et al., *The Effect of a School Entry Law on Mumps Activity in a School District*, 257 J. AM. MED. ASS'N 2455 (1987); Plotkin & Wharton, *supra* note 116, at 283. If mumps vaccination ceased, the number of cases probably would quickly climb back to pre-immunization levels since mumps spreads easily among unvaccinated individuals. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16.

136. See Mootrey et al., *supra* note 70, at 18–12. The 2001 Summary of Notifiable Diseases reported that U.S. rubella cases were down to just 23 in 2001. See *Summary of Notifiable Diseases—United States, 2001*, *supra* note 97.

137. See CDC, *IF WE STOPPED VACCINATIONS*, *supra* note 16.

138. See *id.*

139. See *Summary of Notifiable Diseases—United States, 2001*, *supra* note 97.

to fear, pregnant women and their unborn children will be placed most at risk if vaccination rates decline in the United States.

• *Poliomyelitis (OPV and IPV Vaccines)*—As recently as the 1950s, polio was the most feared disease in the United States. Once infected, many victims developed paralysis in their arms or legs, while others died because the muscles used for breathing were paralyzed. A 1916 epidemic killed 6,000 Americans and paralyzed 27,000 more.¹⁴⁰ In the early 1950s, nearly 2,000 deaths and 16,000 paralytic polio cases were still reported annually.¹⁴¹ Those children fortunate enough to survive were left in braces, crutches, wheelchairs, and iron lungs. Mass vaccination was begun in 1955 after Jonas Salk's landmark work on the inactivated polio vaccine (IPV), dropping the number of polio victims to 3,000 by 1960.¹⁴² Albert Sabin's live oral polio vaccine (OPV) became the immunization of choice by 1964,¹⁴³ and by 1979, a grand total of 10 cases were reported in all of the United States.¹⁴⁴ The tide turned again on polio vaccine preference in April 2000, as the live oral vaccine was discontinued due to a small risk of the virus mutating into a more virulent form and actually transmitting polio. Thus, the Advisory Committee on Immunization Practices (ACIP) now recommends routine vaccination by injection with the inactivated vaccine instead.¹⁴⁵

Thankfully, no wild polio virus has been reported in the United States for over 20 years now. Elsewhere on the planet, significant progress has been made toward the control of the polio virus. While it has been reduced worldwide by more than 90 percent since its peak,¹⁴⁶ polio continues to wreak devastation in countries like India, afflicting thousands annually.¹⁴⁷

140. See Polio Vaccine Information Statement, *supra* note 70.

141. See *Impact of Vaccines*, *supra* note 18 (citing CDC data).

142. See Polio Vaccine Information Statement, *supra* note 70.

143. See Robbins, *supra* note 77, at 18.

144. See Polio Vaccine Information Statement, *supra* note 70.

145. See WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–6. The IPV contains killed virus and is given as an injection into the leg or arm. *Id.*

146. See SCHNEIDER, *supra* note 17, at 137.

147. See Allen, *supra* note 78 (noting that 68% of the world's polio cases occur in the northern regions of India); CDC, IF WE STOPPED VACCINATIONS, *supra* note 16 (noting that as of 1999, nearly 3,000 polio cases were reported across the world). See also Amy Waldman, *Distrust Reopens the Door for Polio in India*, N.Y. TIMES, Jan. 19, 2003, at A1 (attributing the alarming rise in polio cases last year in India to distrust of government—a rumor was spread that the oral vaccine was part of a government population control program). However, despite these cases, United Nations health officials believe that polio can be eradicated globally by 2005 if currently afflicted countries give “full backing to extensive immunization campaigns.” See U.N. Says It Can Eradicate Polio by 2005, REUTERS, July 29, 2003, available at http://story.news.yahoo.com/news?tmpl=story&cid=594&ncid=594&e=2&u=/nm/20030729/hl_nm/health_polio_dc (on file with the University of Michigan Journal of Law Reform).

• *Influenza (the Flu)*—The influenza virus spreads easily from person to person through coughing and sneezing. It leads to pneumonia and heart problems in some cases, and can be extremely serious for children with chronic illnesses such as asthma, heart disease or diabetes. In the winter of 1918–1919, the devastating swine flu virus killed approximately 30 million people worldwide, including 500,000 in the United States.¹⁴⁸ Other tragic outbreaks occurred in 1957, when the Asian flu killed 69,800 Americans, and in 1968, when the Hong Kong flu took 33,800 lives.¹⁴⁹ The flu still causes 20,000 deaths and 114,000 hospitalizations per year to this day.¹⁵⁰

Vaccination against influenza can be fairly successful—though the flu virus varies and mutates year-to-year, making it more difficult to develop effective vaccines for it than for other diseases.¹⁵¹ Still, thousands of lives are saved each year by vaccinating vulnerable populations, and it has been estimated that \$117 in healthcare costs per influenza vaccine are averted because of immunization.¹⁵² Nevertheless, most states do not require the influenza vaccination, but merely recommend it for individuals who are at high risk for complicated diseases, including pregnant women and the elderly.¹⁵³

148. See Victoria Stagg Elliot, *Planning for Next Flu Pandemic Still a Tough Sell*, AM. MED. NEWS July 1, 2002, available at <http://www.ama-assn.org/amednews/2002/07/01/hlsb0701.htm> (citing to Centers for Disease Control and Prevention statistics for U.S. death figures from the flu) (on file with the University of Michigan Journal of Law Reform). See also Jill Lee, *Containing the Hong Kong Poultry Flu Outbreak*, AGRICULTURAL RES., Dec. 1998, at 16, available at <http://www.ars.usda.gov/is/AR/archive/dec98/flu1298.htm> (noting that 30 million people worldwide were killed in the 1918 Spanish flu epidemic).

149. See Elliot, *supra* note 148.

150. See Zimmerman et al., *supra* note 97, at S14 (citing to Centers for Disease Control and Prevention, *Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices*, 51 MORBIDITY & MORTALITY WKLY. REP. 1 (2002)).

151. See Laura Lane, *New Flu Vaccine Could Provide Longer Protection*, CNN.COM, Sept. 27, 1999, available at <http://www.cnn.com/HEALTH/9909/27/universal.flu/> (noting that health officials must develop new flu vaccines for every season because the virus mutates quickly) (on file with the University of Michigan Journal of Law Reform).

152. See M.A. Riddiough et al., *Influenza Vaccination: Cost Effectiveness and Public Policy*, 249 J. AM. MED. ASS'N 3189 (1983); *Economic Analysis of Influenza Vaccination and Antiviral Treatment for Healthy Working Adults*, 137 ANNALS INTERN. MED. 225 (2002) (finding that "vaccination is cost-beneficial in most influenza seasons). Other studies have confirmed that influenza vaccination is cost-effective, resulting in a net savings of \$4 per child vaccinated when individually initiated, and \$35 for group-based vaccination. See T. White, *Potential Cost Savings Attributable to Influenza Vaccination of School-aged Children*, 103 PEDIATRICS e73 (1999). But c.f. Carolyn Buxton Bridges et al., *Effectiveness and Cost-Benefit of Influenza Vaccination of Healthy Working Adults, A Randomized Controlled Trial*, 284 J. AM. MED. ASS'N 1655 (2000) (raising questions about the net cost-benefit impact of influenza vaccine for healthy adults under 65).

153. See, e.g., WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–7.

• *Hepatitis A and B*—Hepatitis A is a disease of the liver caused by a virus found in the stool of an infected individual.¹⁵⁴ It spreads when a person puts something into her mouth (food, water, hands or an object) that has just a minute amount of infected feces on it.¹⁵⁵ It moves easily from person to person in the same household or childcare setting.¹⁵⁶

Hepatitis B is a far more serious liver infection that can be transmitted from person to person through blood or sexual body fluids.¹⁵⁷ More than 2 billion people worldwide have been infected with the hepatitis B virus at some point in their lives, and 350 million remain life-long carriers of the disease.¹⁵⁸ An infected mother has a 90% chance of passing the virus to her newborn during birth.¹⁵⁹ Symptoms of hepatitis B include nausea, vomiting, abdominal pain and jaundice.¹⁶⁰ More invidiously, an infected person may not develop any symptoms at all, making it quite easy to unknowingly spread the virus. In its severe stages, hepatitis B can cause chronic liver disease and even liver cancer.

The vaccine for hepatitis A is not required in many states but merely recommended.¹⁶¹ The hepatitis B vaccine is generally mandatory, and has been licensed since 1982.¹⁶² The vaccine has cut the number of acute hepatitis B cases by 60% in the last ten years, from 21,102 in 1990 to 7,843 in 2001.¹⁶³ Still, approximately 12.5% of Americans are infected at some point in their lifetime, and about 5,000 die annually from hepatitis B-related liver disease (not to mention the over \$700 million in medical and work loss costs incurred).¹⁶⁴

• *Haemophilus Influenzae type b* (“Hib”)—Hib bacteria can exist in the nose and throat of many people without making them ill, but can cause serious illness in preschool-aged children.¹⁶⁵ Hib disease

154. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

155. *See id.*

156. *See id.*

157. *See id.*

158. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16. One million of those life-long carriers die each year from hepatitis B-related liver disease and liver cancer. *See id.*

159. WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–7. Infected babies have a 90% chance of becoming chronically infected and a 25% chance of dying of chronic liver disease as an adult. *See id.*

160. See Francis J. Mahoney & Mark Kane, *Hepatitis B Vaccine*, in VACCINES 159 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

161. *See, e.g.*, WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–7.

162. *See id.*

163. *See Summary of Notifiable Diseases—United States, 2001*, *supra* note 97.

164. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

165. See WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–6.

can cause infections of the joints, skin and blood, and can lead to meningitis (swelling of the brain and spinal cord), brain damage and even death.¹⁶⁶ It can also cause epiglottitis, a swelling in the throat that is potentially lethal.¹⁶⁷

A conjugated Hib vaccine was developed in 1987 and has dramatically reduced cases of the disease.¹⁶⁸ Before the vaccine, Hib was the most common cause of postnatal mental retardation and bacterial meningitis in children under five.¹⁶⁹ Approximately 20,000 children per year contracted severe Hib disease and up to 1,000 died.¹⁷⁰ Survivors were frequently left with seizures, mental retardation or deafness.¹⁷¹ Today, Hib invasive disease has been nearly eliminated among American children due to widespread vaccination, with a total of only 125 cases reported in 1998.¹⁷²

• *Pneumococcal Disease*—Now that Hib disease has been greatly reduced, invasive pneumococcal disease has become the leading cause of meningitis in America.¹⁷³ It is spread from person to person through respiratory droplets, and can cause serious blood infections and pneumonia.¹⁷⁴

Before the vaccine was made available, each year pneumococcal infections caused 700 cases of meningitis, 13,000 blood infections and 5 million ear infections.¹⁷⁵ Worse, many of the infections were difficult to treat because the responsible bacteria have become resistant to the drugs used to combat them.¹⁷⁶ Today, pneumococcal disease is on the decline, but still produces 200 deaths each year

166. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

167. See WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–6.

168. See *id.* at 2–7. See also CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

169. See *Impact of Vaccines*, *supra* note 18 (citing S.L. Cochi & J.I. Ward, *Haemophilus Influenzae Type B*, in BACTERIAL INFECTIONS OF HUMANS (A.S. Evans & P.S. Brachman eds., 1991); M. Yeargin-Allsopp et al., *Reported Biomedical Causes and Associated Medical Conditions for Mental Retardation Among 10-Year-Old Children, Metropolitan Atlanta, 1985–1987*, 39 DEVELOPMENTAL MED. & NEUROL. 142 (1997)).

170. See *Haemophilus Influenzae* type b Vaccine Information Statement, 42 U.S.C. § 300aa-26 (1998).

171. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

172. See *Impact of Vaccines*, *supra* note 18 (only 54 were confirmed Hib cases, the others were of unknown serotype). See also *Haemophilus Influenzae* type b Vaccine Information Statement, *supra* note 170. In Washington state alone, reports of Hib disease went from 271 in 1987 to just 10 by 1994. See *id.*

173. See *Pneumococcal Conjugate Vaccine Information Statement*, 42 U.S.C. § 300aa-26 (2002).

174. See *id.*

175. See *id.*

176. See *id.*

among children under 5 and is the primary cause of bacterial meningitis in the U.S.¹⁷⁷ The vaccine is not required in many states.¹⁷⁸

• *Varicella (Chicken Pox)*—Varicella, ubiquitously known as the chicken pox, is often viewed as a rite of childhood because the vast majority of Americans are infected before they reach adulthood.¹⁷⁹ It usually produces only an itchy skin rash with telltale blisters and fever, but can also lead to serious skin infections, pneumonia and swelling of the brain.¹⁸⁰ Moreover, it can be severe in infants and adults with weakened immune systems, hospitalizing 11,000 people each year from complications and killing an average of 100 children and adults annually.¹⁸¹

The varicella vaccine has been available in the United States only since 1995.¹⁸² Perhaps because of how common chicken pox is (4 million cases each year prior to the vaccine's availability),¹⁸³ it is not perceived by many as a particularly serious illness worthy of compulsory immunization.¹⁸⁴ Vaccination rates have therefore been low, reaching only 67% among children 19–35 months old as of 2000.¹⁸⁵ Many American children and adults continue to die from the disease, leading Centers for Disease Control (CDC) officials to recently declare that preventing chicken pox-related deaths is now a “public health priority.”¹⁸⁶

2. *Large-Scale Vaccinations Save Resources*—As an obvious corollary to the health benefits detailed above, mass vaccinations in America have yielded tremendous financial savings. Various

177. See *id.*

178. See, e.g., WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–7.

179. See Anne A. Gershon et al., *Varicella Vaccine*, in VACCINES 475, 481 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

180. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

181. See CENTERS FOR DISEASE CONTROL, VARICELLA DISEASE AND HERPES ZOSTER, CLINICAL QUESTIONS AND ANSWERS, available at <http://www.cdc.gov/nip/diseases/varicella/faqs-clinic-disease.htm> [hereinafter CDC, VARICELLA DISEASE AND HERPES ZOSTER] (on file with the University of Michigan Journal of Law Reform).

182. The vaccine received approval from European countries much earlier than the FDA granted its authorization in America, and had proven itself to be safe and effective. See P. LaRussa, *The Success of Varicella Vaccine*, 31 PEDIATRIC ANNALS 710 (2002). But c.f. K. Galil et al., *Outbreak of Varicella at a Day-Care Center Despite Vaccination*, 347 NEW ENG. J. MED. 1909 (2002).

183. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

184. See CDC, VARICELLA DISEASE AND HERPES ZOSTER, *supra* note 181 (noting that varicella is “frequently perceived as a disease that does not cause serious illness”).

185. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

186. See Megan Rauscher, *U.S. Health Officials Concerned by Chickenpox Deaths*, REUTERS, June 12, 2003, available at <http://www.vaccinationnews.com/DailyNews/2003/June/15/USHealthOfficialsConcerned15.htm> (on file with the University of Michigan Journal of Law Reform).

methods have been utilized to estimate the resources saved due to immunizations, including benefit-risk, benefit-cost, and cost-effectiveness analysis.¹⁸⁷

These systematic analyses have demonstrated the financial and risk reduction ramifications generated by wide-scale vaccination programs.¹⁸⁸ Vaccine-preventable diseases cost 16 times more in medical-related costs than do the vaccines that prevent those diseases.¹⁸⁹ The measles vaccine alone has saved the United States billions of dollars since its 1963 introduction.¹⁹⁰ For every \$1 spent on the MMR vaccine, \$7 to \$14 dollars are saved.¹⁹¹ Each dollar spent on the DTaP vaccine saves society \$27.¹⁹² Medical experts have estimated that the cost-per-life-saved from routine infant hepatitis B vaccination is a mere \$1522,¹⁹³ a startlingly low figure when compared to cost-per-life-saved data for other U.S. health and safety regulations.¹⁹⁴ The common influenza vaccine results in a direct cost savings of \$117 per vaccine per year when given to

187. See Dudgeon et al., *supra* note 38, at 61. Benefit-risk studies are focused on a comparison of vaccinated and non-vaccinated populations relative to absolute numbers or to overall rates of mortality and morbidity. Benefit-cost studies seek to consider all benefits and risks in quantifiable, economic terms. Cost-effectiveness studies involve comparing the total cost of vaccines with overall gains in prevention of disease and life expectancy. *See id.*

188. See Plotkin & Wharton, *supra* note 116, at 284.

189. See WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS, *supra* note 3.

190. See Redd et al., *supra* note 111, at 246 (citing Bloch et al., *supra* note 131; HATZIANDREU ET AL., *supra* note 131). The financial consequences of not vaccinating children against measles are displayed quite clearly by the nationwide 1989–91 outbreak, which caused 44,000 days of hospitalization and resulted in \$100 million in direct medical costs alone. This figure does not include indirect costs to families, such as lost days of work, school or child care. See WASHINGTON DOH, CHILDHOOD IMMUNIZATIONS, *supra* note 3.

191. Plotkin & Wharton, *supra* note 116, at 284 (citing J.P. Koplan & S.R. Preblud, *A Benefit-Cost Analysis of Mumps Vaccine*, 136 AM. J. DIS. CHILD. 362 (1982); C.C. White et al., *Benefits, Risks and Costs of Immunization for Measles, Mumps and Rubella*, 75 AM. J. PUB. HEALTH 739 (1985)). A more recent study concluded the cost-benefit ratio for direct costs of the mumps vaccine is 6.1 and for both direct and indirect costs of the mumps vaccine is 13.0. The same study found that the cost-benefit ratio for the MMR vaccine is 16.3 for direct costs only and 21.3 for both direct and indirect costs. *See* Plotkin & Wharton, *supra* note 116, at 284 (citing unpublished data from the Centers for Disease Control and Prevention). *See also* CENTERS FOR PUBLIC HEALTH RESEARCH AND EVALUATION, *A COST BENEFIT ANALYSIS OF THE MEASLES-MUMPS-RUBELLA (MMR) VACCINE* (1994) (noting that every dollar spent on the vaccine saved \$10.30 in direct medical costs and \$3.20 in indirect societal costs).

192. *See* Editorial, *Preventative Medicine*, N.Y. TIMES, Aug. 18, 2003, at A14.

193. *See* Zimmerman et al., *supra* note 97, at S2. *See also* B.S. Bloom et al., *A Reappraisal of Hepatitis B Virus Vaccination Strategies Using Cost-Effectiveness Analysis*, 118 ANNALS INTERN. MED. 298 (1993).

194. *See* Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 986–87 (2001) (citing to data indicating that numerous federal health and safety regulations cost hundreds of millions of dollars per life saved).

vulnerable populations.¹⁹⁵ Vaccines for poliomyelitis and congenital rubella have resulted in trillions of dollars in savings, not to mention the avoidance of inhumane suffering previously endured by thousands of handicapped and paralyzed children.¹⁹⁶ Moreover, Koplan and his colleagues have produced substantial evidence over multiple studies regarding the cost-effectiveness of immunizations for diphtheria, tetanus, pertussis and measles.¹⁹⁷

Today, the resource ramifications of mass vaccination programs are rarely questioned, though also rarely appreciated. Unfortunately, American adults *contracting* vaccine-preventable diseases still result in \$10 billion worth of unnecessary healthcare costs and more than 30,000 otherwise avoidable U.S. deaths each year.¹⁹⁸ With continued societal complacency, the immense financial resources saved by vaccines may be put in serious jeopardy.

C. State and Federal Involvement in Passing Compulsory Vaccination Laws

Because of the health and welfare benefits made possible by vaccines, all fifty states have enacted compulsory vaccination laws¹⁹⁹

195. See Riddiough et al., *supra* note 152; White, *supra* note 152 (finding that vaccination against influenza resulted in a net savings of \$4 per child vaccinated where the individual initiates vaccination, and \$35 net savings for group-based vaccination). *But c.f.* Bridges et al., *supra* note 152 (noting that for healthy adults under 65 routine influenza vaccination may not save money overall compared to nonvaccination).

196. See Dudgeon et al., *supra* note 38, at 61. See also CENTERS FOR PUBLIC HEALTH RESEARCH AND EVALUATION, A COST BENEFIT ANALYSIS OF THE OPV VACCINE (1994) (noting that even as late as 1994, every dollar spent to administer the oral polio vaccine saved \$3.40 in direct medical costs and \$2.74 in indirect societal costs). The United States spends roughly \$200 million annually on polio immunizations, but the thousands of lives and millions of dollars in resources saved makes this expenditure more than worthwhile. See SCHNEIDER, *supra* note 17, at 137-38 (citing L. Schlein, *Hunting Down the Last of the Poliovirus*, 279 SCI. 168 (1998)).

197. See J.P. Koplan, *Benefits, Risks and Costs of Immunization Programmes: The Value of Preventative Medicine*, 110 CIBA FOUND. SYMP. 55 (1985); J.P. Koplan & N.W. Axnick, *Benefits, Risks and Costs of Viral Vaccines*, 28 PROG. MED. VIROL. 180 (1982); J.P. Koplan et al., *Pertussis Vaccine—An Analysis of Benefits, Risks and Costs*, 301 NEW ENG. J. MED. 906 (1979); J.P. Koplan & C.C. White, *An Update of the Benefits and Costs of Measles and Rubella Immunization*, in *CONQUEST OF AGENTS THAT ENDANGER THE BRAIN* (E.M. Gruenberg ed., 1984).

198. See Yvonne A. Maldonado, *Current Controversies in Vaccination: Vaccine Safety*, 288 J. AM. MED. ASS'N 3155 (2002).

199. See Dudgeon et al., *supra* note 38, at 59; Hodge & Gostin, *supra* note 26, at 874 n.233. The laws require proof of certain immunizations prior to a child's entry into daycare or school, and provide for exclusion of children not in conformity. See Walter A. Orenstein & Alan R. Hinman, *The Immunization System in the United States—The Role of School Immunization Laws*, 17 VACCINE s19 (1999).

—though 48 allow religious exemptions and over a dozen provide philosophical opt-outs.

The first strides in the enactment of American vaccination laws were taken in the early 1800s. Massachusetts was the first state to proactively promote the use of immunizations in the war against smallpox.²⁰⁰ The federal government soon made its first foray into vaccination policy, though it was short-lived. A federal law encouraging vaccination was passed in 1813,²⁰¹ but was repealed just nine years later due largely to the view that government should only intervene in health concerns during times of emergency.²⁰²

It was not until the mid-1900s that federal and state governments demonstrated consistent resolve in their vaccination policy. In 1955 and 1956, after Salk's oral polio vaccine breakthrough, Congress appropriated funds to the CDC to help states and local communities purchase and administer vaccines.²⁰³ President John F. Kennedy sent the Vaccination Assistance Act to Congress in 1962, and its passage allowed the CDC to support mass immunization campaigns and to initiate maintenance programs.²⁰⁴

In the late 1960s the modern era of compulsory state immunization laws took off, as data showed that states with mandatory measles vaccination requirements had 40% to 51% lower rates of the disease than did states without such regulations.²⁰⁵ In response, a number of states made vaccination against measles, poliomyelitis, diphtheria, pertussis, and tetanus a prerequisite to school entry.²⁰⁶ In 1979, federal immunization grant funds increased to \$35 million—a dramatic increase compared to \$17 million in 1977 and

200. See JOHN DUFFY, *THE SANITARIANS: A HISTORY OF AMERICAN PUBLIC HEALTH* 54 (1990). In 1802, the Boston Board of Health sponsored a public test of Jenner's inoculation and a few years later the state passed a law requiring each town without a board of health to appoint a vaccination committee. These committees and the local boards of health were charged with supervising the vaccination of all residents against the deadly illness. *Id.*

201. See *id.* at 56.

202. See *id.*

203. See Walter A. Orenstein et al., *Public Health Considerations—United States*, in *VACCINES* 1011 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999). The Polio Vaccination Assistance Act provided for vaccines instead of cash to be furnished directly to state and local health departments, and that personnel instead of dollars could be furnished to grantees. However, no provision was made in the Act to continue a program of support for immunizations, and direct delivery of immunization services were not supported by the federal government until 1992. See *id.*

204. See *id.* at 1011.

205. See Edwards, *supra* note 36 (discussing the modern era of compulsory vaccination laws, which did not occur until the 1960s and 1970s) (citing *Measles—United States*, 26 *MORBIDITY & MORTALITY WKLY. REP.* 11–109 (1977)).

206. See Dudgeon et al., *supra* note 38, at 59.

just \$5 million in 1976.²⁰⁷ At the same time, the federal government undertook an effort to enact school immunization requirements in states that did not have them and to enforce those already in place.²⁰⁸ Soon, all fifty states had enacted and enforced school entry immunization requirements.²⁰⁹ The laws yielded quick results: by 1981, 95% of children entering school had been immunized.²¹⁰ Today, every state has a series of compulsory and recommended vaccines, with all requiring evidence of vaccination against diphtheria, measles, rubella and polio (at a minimum) prior to day care or school entry.²¹¹ However, in recent years, legislatures have expanded allowable exemptions to immunization laws in an effort to balance public safety with individual rights and liberties.²¹²

D. But Are Compulsory Vaccination Laws Constitutional?

While the federal and state governments adopted aggressive pro-vaccination policies that yielded quick results, the constitutionality of compulsory vaccination requirements was another matter. Not surprisingly, mandatory vaccination regulations encountered stiff resistance, as groups such as the Antivaccination League strongly opposed the initial passage of these laws, challenged them in court, and often refused to comply.²¹³ The strong belief in human autonomy and liberty upon which the United States was founded fueled the fire, as opponents raised arguments based on freedom from government interference and the right to do what they wished with their bodies.²¹⁴ The debate came to a head before the Supreme

207. See Orenstein et al., *supra* note 203, at 1011.

208. See *id.* at 1011–12.

209. See *id.* at 1011.

210. See *id.* Laws increased immunization rates by an average of 15% with a range of 5% to 35% depending upon the vaccine, location, and age of recipient. See P.A. Briss et al., Task Force on Community Preventative Services, *Reviews of Evidence Regarding Interventions to Improve Vaccination Coverage in Children, Adolescents, and Adults*, 18 AM. J. PREVENTATIVE MED. 97 (2000).

211. See Edwards, *supra* note 36. Many other vaccines are required in most states, but almost all allow exemptions for certain groups. Furthermore, since many vaccines are given in combination, the requirement that children be vaccinated against diphtheria and measles effectively encompasses their combined counterparts: the DTaP vaccine covers diphtheria, tetanus and pertussis, and the MMR vaccine protects against measles, mumps and rubella.

212. For a list of which states allow religious and/or philosophical exemptions, see *infra* Part II.H.

213. See Hodge & Gostin, *supra* note 26, at 851.

214. See *id.* at 844–45.

Court just after the turn of the 20th century.²¹⁵ In the case of *Jacobson v. Massachusetts*,²¹⁶ the Court held that the State's police power to protect the public's health included the right to require that all citizens of the city of Cambridge receive a smallpox vaccination.²¹⁷ While the Court acknowledged that individual liberty rights prevent state intrusion in some instances, it held that individual rights cannot themselves intrude upon other people's rights. Thus, despite passionate resistance, the Court made clear that when the health concerns of the larger community are at stake, the state may indeed infringe upon individual rights.²¹⁸

Subsequent cases have affirmed the principle behind *Jacobson*. In the famous "Typhoid Mary" episode shortly afterwards, an otherwise healthy woman (Mary Mallon) was quarantined against her will by the state of New York because of officials' beliefs that she was a potential carrier of the typhoid disease, and therefore represented a danger to the community's health.²¹⁹ In 1910, a Texas

215. State courts had previously considered vaccination cases before *Jacobson*. See, e.g., *Hazen v. Strong*, 2 Vt. 427 (1830) (local town council had authority to pay for vaccination of persons exposed even though there were no cases of smallpox in the community).

216. *Jacobson v. Massachusetts*, 197 U.S. 11, 25–27 (1905).

217. See *id.* at 25–30. A decade prior, a Pennsylvania town's school board regulation prohibiting children not vaccinated against smallpox from attending school was also found to be reasonable based on a current outbreak and expert opinions on the vaccine's efficacy. See *Duffield v. Sch. Dist.*, 29 A. 742, 743 (Pa. 1894).

218. While individual rights may give way to the greater community interest, the Court noted that certain protections for the individual must be accommodated consistent with liberty principles under the Due Process Clause of the Fourteenth Amendment. In addition, the vaccination requirement at issue in *Jacobson* did at least exempt children with adverse medical conditions. See *Jacobson*, 197 U.S. at 12, 30. However, other courts were less accommodating of the rights of vaccine opponents. See *Viemester v. White*, 84 N.Y.S. 712, 713–14, 716 (1903), *aff'd*, 72 N.E. 97, 98–99 (1904) (holding that no constitutional right to an education exists in the New York Constitution and thus, there is no limit on the type of reasonable regulation (including mandatory vaccination requirements) that may be imposed on public education by the legislature). Similarly, the right to a public education under Arizona's state constitution is not offended by the Health Department's exclusion of unvaccinated children from school. See *Maricopa County Health Dep't v. Harmon*, 750 P.2d 1364, 1368–69 (Ariz. 1987) (holding that the health department had authority to exclude unvaccinated children from school even if there were no reported cases of the disease in question and did so without violating the right to public education in the Arizona Constitution).

219. See JUDITH WALZER LEAVITT, *TYPHOID MARY: CAPTIVE TO THE PUBLIC'S HEALTH* (1996). Mary's case was a far more difficult one than that presented in *Jacobson*, because never before had officers of the state taken away a healthy person's physical liberty in the name of protecting the public's health. See *id.* Ironically, this year's SARS epidemic again raises the state's power to quarantine potentially infectious individuals on the grounds that they may pose a threat to the public health and welfare. See Jon Herskovitz, *Texas Air Base Quarantines 11 on SARS Concern*, REUTERS, July 11, 2003, available at <http://story.news.yahoo.com/news?tmpl=story&cid=578&ncid=578&e=5&u=/nm/20030712> (on file with the University of Michigan Journal of Law Reform).

court held that mandatory school vaccination laws did not constitute an illegal search and seizure in violation of the Fourth Amendment of the state constitution.²²⁰ An Equal Protection challenge to vaccination regulations was denied in *Zucht v. King*, as the U.S. Supreme Court ruled that vaccination laws do not discriminate against schoolchildren to the exclusion of others similarly situated (i.e., children not enrolled in school).²²¹ In the case of *Adams v. Milwaukee*, Justice Brandeis reaffirmed *Jacobson's* holding that states may delegate the power to order vaccinations to local municipalities, and that broad discretion must be granted in the application and enforcement of the resulting public health regulations.²²² In *Prince v. Massachusetts*, the Supreme Court held that the First Amendment's Free Exercise Clause does not allow for the right to expose the community or one's children to harm from disease.²²³ An Arkansas court later affirmed that school vaccination requirements do not deprive individuals of liberty and property interests without due process of the law.²²⁴ Moreover, even where a parent objects to compulsory vaccination, a child does not have an absolute right to enter school to receive an education.²²⁵ Clearly then, the rights of individuals to be free from unwanted government interference in the form of compulsory vaccinations have been severely limited by the courts where the public health is at stake.

But what about the constitutionality of compulsory vaccinations where no exemptions at all are provided—i.e., neither for philosophical nor religious reasons? Again, the judiciary has held that individual rights may be restricted in the name of the public welfare without violating the Constitution. In Arkansas, parents have no legal right to prevent vaccinations of children when required to

220. See *McSween v. Bd. of Sch. Trs.*, 129 S.W. 206, 207–08 (Tex. Civ. App. 1910).

221. See *Zucht v. King*, 260 U.S. 174, 176 (1922) (“Long before this suit was instituted, *Jacobson* . . . had settled that it is within the police power of a state to provide for compulsory vaccination.”).

222. See *Adams v. Milwaukee*, 228 U.S. 572, 581–82 (1913). A New Hampshire court also relied upon *Jacobson* in rejecting a father's claim that vaccination of his daughter should not be required based on his belief that it would “endanger her health and life” by “performing a surgical operation by injecting a poison . . . into [her] blood.” See *Cram v. Sch. Bd. of Manchester*, 136 A. 263, 263–64 (N.H. 1927).

223. See *Prince v. Massachusetts*, 321 U.S. 158, 169–70 (1944) (holding that a mother can be prosecuted under child labor laws for using her children to distribute religious literature since they were being placed in harm's way).

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

225. See *State ex rel. Mack v. Bd. of Educ.*, 204 N.E.2d 86, 90 (Ohio Ct. App. 1963) (finding that a school board has authority to make and enforce rules and regulations to secure immunizations against polio, smallpox, pertussis and tetanus).

attend school even if their objections are based on good faith (but nationally unrecognized) religious beliefs.²²⁶ Furthermore, a mandatory vaccination regulation with no religious exemption was held constitutional because the right of free exercise is subject to reasonable regulation for the good of the community as a whole.²²⁷ A New York court has similarly ruled that its vaccination statute does not interfere with freedom to worship.²²⁸ Some state courts have held that parents must be members of a “nationally recognized and established church or religious denomination” in order to claim an exemption,²²⁹ but others have found that similar regulations violate the Equal Protection Clause of the Constitution by giving preference to certain religions over others.²³⁰ Moreover, some courts have

226. See *Cude v. State*, 377 S.W.2d 816, 818 (Ark. 1964). Arkansas was one of only three states to ban religious exemptions to vaccination requirements. As of 2000, it allowed such opt-outs but only if parents met a relatively strict standard: “immunization [must] conflict[] with the religious tenets and practices of a *recognized* church or religious denomination of which the parent is an adherent or member”—i.e., not all, and in practice, very few religions qualify. See ARK. CODE ANN. § 6-18702 (Michie 1999) (emphasis added). However, just last year, the constitutionality of such a strict religious exemption was challenged. In *Boone v. Boozman*, an Arkansas federal district court held that the state’s religious exemption violated a mothers’ Free Exercise and Establishment Clause rights by limiting opt-outs to members of “recognized” churches or religious denominations. However, it severed the remaining portion of the compulsory immunization statute, effectively declaring that required immunization without any religious exemptions was constitutional. See *Boone v. Boozman*, 217 F. Supp. 2d 938, 946–51, 954 (E.D. Ark. 2002).

227. See *Wright v. DeWitt Sch. Dist.*, 385 S.W.2d 644, 649 (Ark. 1965).

228. See *McCartney v. Austin*, 293 N.Y.S.2d 188, 200 (N.Y. 1968) (holding that Roman Catholic faith does not proscribe vaccination; therefore, New York law does not interfere with freedom to worship). Furthermore, as recently as 2000, New York courts have held that a Catholic parent’s belief opposed to vaccinations was “personal” and medical and therefore not an adequate basis to recover damages from the Board of Education based on its refusal to accept the “religious” exemption. See *Farina v. Bd. of Educ.*, 116 F. Supp. 2d 503, 508 (S.D.N.Y. 2000). One should note though that New York’s compulsory vaccination statute allows religious exemptions in other legitimate cases. See N.Y. Pub. Health Law § 2164; see also *Bowden v. Iona Grammar Sch.* 726 N.Y.S.2d 685, 686–87 (N.Y. App. Div. 2001) (holding that parents who followed practices of the Temple of the Healing Spirit are entitled to religious exemption because state statute did not qualify which religions were eligible).

229. See *Kleid v. Bd. of Educ.*, 406 F. Supp. 902, 904 (W.D. Ky. 1976).

230. See *Dalli v. Bd. of Educ.*, 267 N.E.2d 219, 222–23 (Mass. 1971) (holding that state exemption for objectors who believe in the “tenets and practices of a recognized church of religious denomination” violates Equal Protection Clause because it discriminates against parents who have sincere, though unrecognized, religious beliefs). See also *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 87–88 (E.D.N.Y. 1987) (holding that the requirement that parents be “bona fide members of a recognized religious organization” to be exempt on religious grounds from school vaccination requirement violates the Establishment Clause); *Boone*, 217 F. Supp. 2d at 946–51, 954 (holding that (1) statute’s religious exemption provision, which only allowed objections based on tenets or practices of “recognized church or religious denomination,” violated mother’s Free Exercise and Establishment Clause rights, but that (2) the severed remainder of statute, requiring immunization without religious exemption, was constitutional).

gone as far as to say that providing any religious exemption violates the Equal Protection Clause because it “discriminate[s] against the great majority of children whose parents have no such religious convictions.”²³¹ Additionally, in response to a growing number of religious practices claiming immunization exemptions, Ohio’s Supreme Court ruled that a parent’s objection to vaccination based on “chiropractic ethics” did not fall under the gambit of Establishment Clause protection.²³² Similarly, the Second Circuit U.S. Court of Appeals found that a parent’s belief that immunization was contrary to nature’s “genetic blueprint” was a secular, not religious, belief, and thus her child’s required vaccination did not violate the Establishment Clause.²³³

However, the common law is not absolute in its support of states’ rights to require vaccinations absent reasonable accommodations, and the trend may be expanding in recent years. A New York federal district court upheld a Jewish parent’s “sincere religious belief” opposing immunizations even though nothing in the Jewish religion prohibits vaccination.²³⁴ Furthermore, in Wyoming, the Department of Health has no authority to insist that a student provide a medical reason for seeking a waiver from immunization,²³⁵ or even to inquire into the sincerity of a parent’s religious objection to vaccination.²³⁶ Finally, despite the rise of new religions which oppose immunization laws, a New York appellate court found that parents who followed the practices of the “Temple of the Healing Spirit” were entitled to a religious exemption.²³⁷

Thus, while caselaw supports both sides of the compulsory vaccination debate, the majority of courts, and especially the U.S.

231. See *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979).

232. See *Hanzel v. Arter*, 625 F. Supp. 1259, 1263–64 (S.D. Ohio 1985) (holding that children not exempt from statutory mandate because religious belief in “chiropractic ethics” does not raise an Establishment Clause defense).

233. See *Mason v. Gen. Brown Cent. Sch. Dist.*, 851 F.2d 47, 53 (2d Cir. 1988) (rejecting parents’ claim for religious exemption as members of the Universal Life Church).

234. See *Berg v. Glen Cove City Sch. Dist.*, 853 F. Supp. 651, 654–55 (E.D.N.Y. 1994) (holding that parents established “irreparable harm” and likelihood of success on their claim that beliefs they held opposing immunization qualified as “religious”).

235. See *Jones ex rel. Jones v. State, Dep’t of Health*, 18 P.3d 1189, 1195 (Wyo. 2001) (holding that proof of a medical contraindication to immunization not required for exemption).

236. See *In re LePage*, 18 P.3d 1177, 1180 (Wyo. 2001). A Florida court has similarly ruled that the State’s Health Department was precluded from inquiring into the sincerity of a mother’s claim for religious exemption. See *Dep’t of Health v. Curry*, 722 So. 2d 874, 878 (Fla. Ct. App. 1998).

237. See *Bowden v. Iona Grammar Sch.*, 726 N.Y.S.2d 685, 686–87 (N.Y. App. Div. 2001) (holding that religious exemption allowed because state statute did not qualify which religions were eligible).

Supreme Court, have come down on the side of substantial deference to states' police power to require immunizations in the interest of the public health. Compulsory vaccination laws thus enjoy broad judicial and constitutional support, but have also become the subject of growing resistance.

II. THE GROWING ANTIVACCINATION MOVEMENT

Despite the judicial proclamations that compulsory vaccination laws do not run afoul of the Constitution or intrude too deeply into individual rights and freedoms, antivaccination sentiments have never been quelled. In fact, opposition to mandatory immunization laws dates back to the very first uses of vaccines.²³⁸ The same year that Jenner published his groundbreaking work, the "Society of Antivaccinationists" was founded upon the belief that vaccination was an "inappropriate meddling in the work of God."²³⁹ The Antivaccination League further resisted smallpox vaccination efforts in the 1800s.²⁴⁰ While the majority of the population eventually became convinced that the smallpox vaccine was beneficial, a vocal antivaccination minority remains unsatisfied to this day.²⁴¹ The concerns raised by opponents historically are similar to many objections voiced in recent years. Antivaccinationists assert the actual medical risks posed by immunizations, as well as their right to religious and personal freedom from unwanted government interference and the protection of their civil liberties.²⁴² Further, some well-meaning parents systematically misperceive or overperceive the magnitude of the risks involved, causing them to decide that the dangers of vaccinating are worse than the benefits.

The antivaccination movement is thus making inroads into the minds of parents today, leading many to believe that the cure may be worse than the disease. Since the illnesses that vaccines combat

238. See Hodge & Gostin, *supra* note 26, at 844–45.

239. See David M. Abbey, *Letters re Antivaccination Web Sites*, 288 J. AM. MED. ASS'N 1717 (2002).

240. See Editorial, *Smallpox—Vaccination: American Anti-Vaccination League Organized*, N.Y. TIMES, Oct. 27, 1885, at 2; Editorial, *Smallpox—American Anti-Vaccination League: Organization: Evil Influence*, N.Y. TIMES, Oct. 28, 1885, at 4; Editorial, *Smallpox—Anti-Vaccination League's Arguments Condemned*, N.Y. TIMES, Apr. 1, 1894, at 4.

241. See Hodge & Gostin, *supra* note 26, at 848.

242. See *id.* at 844–45; Wolfe et al., *supra* note 22, at 3247. In addition to the objections mentioned above, many modern day opponents advocate homeopathic alternatives to vaccines as an effective means to combat disease. See *id.*

are no longer major killers in the United States, far greater attention is paid instead to the risks that immunizations present. Moreover, it is difficult to distinguish accurate safety and risk information from that which is unsupported by mainstream medical research. Growing beliefs in individualism, civil liberties and freedom from government intrusion add to the resistance.²⁴³ Lawsuits based on adverse vaccine events have skyrocketed, threatening manufacturers with bankruptcy.²⁴⁴ Though Congress passed the National Childhood Vaccine Injury Act to curtail this problem in the mid-1980s, individual exemptions to compulsory vaccination laws have increased unabated. Forty-eight states now allow parents to opt out their children for religious reasons,²⁴⁵ the validity of which are questioned by some critics.²⁴⁶ More than a dozen states provide “philosophical” opt-outs as well, often requiring no more than the mere checking of a box to legally enroll one’s child in school without any immunizations.²⁴⁷ Not surprisingly, “hot spots” are now cropping up all over the country where as many as 1 in 5 children are not protected against the killer diseases of the past.²⁴⁸

A. Medical Risks Posed by Vaccines

While vaccines are relatively safe, all carry risks of adverse reactions, most of which are minimal but some of which are serious.²⁴⁹

As a starting point, it is important to realize that absolutely nothing in life is “100% safe”²⁵⁰—unavoidable risks come with every product used or ingested. Even when all reasonable precautions are taken in the manufacture of vaccinations, it is inevitable that adverse reactions will occur.²⁵¹ The great majority of side effects are

243. See Hodge & Gostin, *supra* note 26, at 834.

244. See Michael Freedman, *The Tort Mess*, FORBES, May 13, 2002, at 90, 94.

245. See Hodge & Gostin, *supra* note 26, at 874 n.233.

246. See, e.g., McNeil, *Worship Optional*, *supra* note 4, at D1 (describing the Congregation of Universal Wisdom, whose tenets include that the “laying on of hands to the vertebrae shall be the sole means of maintaining the life force.” Therefore, “[n]o member of the Congregation shall have injected, ingested or infused into the body any foreign materials of unhealthy or unnatural composition [i.e., vaccines].”).

247. See McNeil, *When Parents Say No*, *supra* note 6, at A12. For a sample “check the box” form, see Exhibit A.

248. See McNeil, *When Parents Say No*, *supra* note 6, at A1. Hot spots run from parts of Washington state to Boulder, Colorado to towns in Missouri and Massachusetts. See *id.*

249. See Maldonado, *supra* note 198, at 3155.

250. See Calandrillo, *supra* note 194, at 979 (describing the infeasibility of a risk-free society).

251. See Dudgeon et al., *supra* note 38, at 61.

local and minor, such as pain, erythema, inflammation and swelling at the injection site.²⁵² These mild complications may occur in up to 50% of vaccines given.²⁵³ Systemic symptoms specific to each particular vaccine may also occur, including fever, headache, irritability, vomiting, diminished activity and other complications.²⁵⁴ For instance, the pertussis vaccine is a rare cause of persistent inconsolable crying, high fever and seizures.²⁵⁵ Other more serious reactions to vaccines may occur in exceedingly rare circumstances, such as severe allergic reactions, deafness or brain damage.²⁵⁶ Even though these serious risks are extremely rare, Congress has enacted legislation to provide compensation to all children injured by immunizations through the National Childhood Vaccine Injury Act.²⁵⁷

A source of particular concern in the last few years regarding vaccination risks is the use of the ethylmercury-based preservative thimerosal. Mercury is a known neurotoxin, and some antivaccinationists have raised alarming allegations that thimerosal causes not only allergies but autism as well.²⁵⁸ Other critics contend that immunizations can lead to multiple sclerosis, sudden infant death

252. See Maldonado, *supra* note 198, at 3155. Information about the potential types of harm and their frequency for every vaccine can be found in Vaccine Information Statements (VIS's) and Advisory Committee on Immunization Practices (ACIP) Recommendations. See 42 U.S.C. § 300aa-26 (requiring that VIS's for the MMR, DTaP, and all other routinely provided childhood immunizations are provided to parents explaining the basic benefits and risks of each particular vaccine).

253. See Maldonado, *supra* note 198, at 3155.

254. See *id.* Mild systemic symptoms associated with the MMR vaccine include fever, mild rash, and swelling of the glands in the cheeks or neck. The DTaP vaccine can produce fever, swelling, soreness or tenderness in the injection site in one in four children, as well as fussiness, tiredness, poor appetite and vomiting. Other side effects can be found by referencing the Vaccine Information Statements for each available vaccine. See, e.g., Measles Mumps Rubella Vaccine Information Statement, 42 U.S.C. § 300aa-26 (2002).

255. See VACCINE EDUCATION CENTER, *supra* note 18. Although these more serious complications can be very frightening for parents, they usually do not result in permanent harm to the child. See *id.*

256. See, e.g., Measles Mumps Rubella Vaccine Information Statement, *supra* note 254. These more severe complications occur at a frequency of one per thousands or millions of doses administered, depending on the vaccine in question. The most dire outcomes are so rare that experts cannot be sure whether they are caused by the vaccine or not. See *id.* See also Maldonado *supra* note 198, at 3155, 3158, Box 2.

257. National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, tit. III, § 311(a), 100 Stat. 3756, codified as amended at 42 U.S.C.A. §§ 300aa-1 to 300aa-34 (2000). See *infra* Part II.G. Of course, monetary compensation is an imperfect substitute for an injury sustained by one's child due to vaccination.

258. See Arthur Allen, *The Not-So-Crackpot Autism Theory*, N.Y. TIMES, Nov. 10, 2002, at F66; Mark Benjamin, *Autism, Vaccine Link Considered*, UPI, May 5, 2003; *Toxic Metal Clue to Autism*, NEW SCIENTIST, June 18, 2003; Fox, *supra* note 23.

syndrome (SIDS), diabetes, asthma and bacterial infections.²⁵⁹ The risk of autism and these other dire complications has never been confirmed conclusively and remains the subject of much controversy and debate.²⁶⁰ Further study is now underway as many antivaccinationists have presented studies linking mercury poisoning to symptoms exhibited by immunized children. In the interest of caution, thimerosal has been removed from all routinely-given vaccines to prevent any further potential risk.²⁶¹

It is crucial that Americans, in order to make sensible healthcare decisions, not lose sight of the fact that the actual risks of vaccines must be compared to the risks of *not* vaccinating—i.e., risk versus risk analysis.²⁶² Most scientists believe that the dangers posed by diseases now preventable through immunizations substantially outweigh the risks introduced by vaccines. In general, risk versus risk analysis indicates that opting to receive vaccinations is approximately one thousand times safer than running the chance of contracting the disease itself in order to avoid an adverse immunization event.²⁶³ The following chart compiled by the CDC illustrates the relative risks of complications from some commonly used vaccines compared to the dangers of the diseases they prevent.²⁶⁴

259. See, e.g., NATIONAL VACCINE INFORMATION CENTER website, available at <http://www.909shot.com> (providing links regarding the connection between vaccines and autism, diabetes, and several other diseases). But see VACCINE EDUCATION CENTER, *supra* note 18 (refuting claims that vaccines cause diabetes, multiple sclerosis, asthma or allergies).

260. See Jane E. Brody, *Vaccines and Autism, Beyond the Fear Factors*, N.Y. TIMES, Mar. 25, 2003, at F7.

261. See *id.* For further discussion of these particular risks and the research regarding them, see *infra*, Part II.C.

262. See generally Calandrillo, *supra* note 194, at 996–98.

263. See INSTITUTE FOR VACCINE SAFETY website, available at <http://www.vaccinesafety.edu/> (click on “FAQs” and follow link to “table” in first answer, citing slide show presentation by Neal Halsey). One should note that while Halsey has long been a supporter of compulsory vaccination, he does not take lightly the arguments made by antivaccinationists regarding the link between thimerosal and autism. Halsey is of the view that “the evidence is [not] convincing now that there has definitely been harm done by thimerosal,” but believes that public health authorities must follow through with current medical studies to see if there is indeed a connection between vaccines and autism, and if there is, they must provide compensation to those families harmed. See Allen, *supra* note 258.

264. See Maldonado, *supra* note 198, at 3158 Box 2 (citing data reproduced from National Immunization Program, Centers for Disease Control and Prevention).

RISK FROM DISEASE (WITHOUT VACCINATION)		RISK FROM VACCINE	
<i>Measles</i> —		<i>MMR Vaccine</i> —	
Pneumonia:	1 in 20	Encephalitis or Severe	1 in 1 million
Encephalitis:	1 in 2,000	Allergic Reaction:	
Death:	1 in 300		
<i>Mumps</i> —			
Encephalitis:	1 in 300		
<i>Rubella</i> —			
Congenital Rubella Syndrome:	1 in 4		
<i>Diphtheria</i> —		<i>DTaP Vaccine</i> —	
Death:	1 in 20	Continuous crying (full recovery):	1 in 100
<i>Tetanus</i> —		Convulsions/shock (full recovery):	1 in 1,750
Death:	3 in 100	Acute Encephalopathy:	0 to 10.5 in 1 million
<i>Pertussis</i> —		Death:	none proven
Pneumonia:	1 in 8		
Encephalitis:	1 in 20		
Death:	1 in 200		

Moreover, Neal Halsey of the Institute for Vaccine Safety prepared the following data to illustrate vaccine risk versus disease risk comparisons:²⁶⁵

**RISK RATIOS FOR SERIOUS ADVERSE EVENTS:
DISEASE VERSUS VACCINE**

VACCINE	ADVERSE EVENT	RISK OF EVENT WITH NO VACCINE	RISK OF EVENT WITH VACCINE	VACCINE: NO VACCINE RISK RATIO
Oral Polio	Paralysis	1 to 5 in 1,000	1 in 1 million	1,000+
Measles	Encephalopathy	1 in 1,000	1 in 1 million	1,000
Varicella	Cerebellar ataxia	4 in 1,000	1 in 1 million	4,000
TT	Death	1 in 10	1 in 1 million+	100,000

265. See INSTITUTE FOR VACCINE SAFETY website, *supra* note 263. While Halsey is a strong proponent of vaccination, he has also recommended removal of thimerosal from vaccines pending further study into the possible link to autism. See Allen, *supra* note 258 (describing Halsey's concern about thimerosal, though he believes there is not enough evidence currently to conclude it is responsible for the rise in autism rates).

Significantly, the data indicate that vaccines are on the order of 1,000 to 100,000 times safer than running the risk of contracting any of the above life-threatening diseases.

Moreover, in the instances where the risks of vaccines have been shown to outweigh their benefits, the CDC has acted quickly to end or alter the relevant vaccination program. When it was discovered that the rotavirus vaccine had the potential to cause intestinal blockage, it was discontinued.²⁶⁶ In addition, in 2000, leading medical experts recommended a change from the live oral polio vaccine to the inactivated polio injection when it became evident that the small risks of the oral version (namely, that it could cause poliomyelitis in rare instances) now outweighed its benefits.²⁶⁷ Finally, erring on the side of safety, the ethylmercury-based preservative thimerosal was removed from all routinely given vaccinations three years ago.²⁶⁸

Thus, when one considers the risks of vaccines versus the risks they avert, CDC data indicate that the public health benefit of preventing deadly diseases significantly outweighs the risk of harm presented by immunizations.

B. Individualism and Freedom from Government Interference

In addition to the potential safety risks associated with immunizations, antivaccinationists raise the classic American values of freedom and individualism as grounds for their objections to compulsory vaccination laws. Groups opposed to government interference in personal lives vociferously argue that no one, especially not the state, can dictate what they can do with their body (or their child's body for that matter). Mandatory vaccination is therefore an unwarranted interference with basic human autonomy and liberty.²⁶⁹ In fact, nearly 4 out of 5 websites opposing vaccination

266. See VACCINE EDUCATION CENTER, *supra* note 18.

267. See *id.* Since eight to ten Americans contracted polio each year from the live oral vaccine itself, it was decided in 2000 to change the recommended course of action to the inactivated polio vaccine. See SCHNEIDER, *supra* note 17, at 137–38 (citing CENTERS FOR DISEASE CONTROL AND PREVENTION, *One Thousand Days Until the Target Date for Global Poliomyelitis Eradication*, 234 MORBIDITY & MORTALITY WKLY. REP. 47 (1998)). See also WASHINGTON DOH, IMMUNIZATION MANUAL, *supra* note 112, at 2–6 (indicating that the oral polio vaccine is no longer given in the U.S. as of April 2000). Even under the “riskier” oral polio vaccine, the risk of approximately eight deaths per year was overwhelmed by the literally thousands of Americans that would have otherwise been afflicted with the crippling disease itself.

268. See Brody, *supra* note 260.

269. See Hodge & Gostin, *supra* note 26, at 844–45.

argue that current U.S. immunization laws are a violation of civil liberties.²⁷⁰ In particular, many cite newly created electronic vaccine registries as an example of “Big Brother” intruding into private lives.²⁷¹ Antivaccinationists further characterize public health authorities as abusive, untrustworthy and paternalistic.²⁷² Resisting forced immunization, on the other hand, is equated with the noble fight against government oppression.²⁷³

These arguments can be found in the earliest vaccination cases, including *Jacobson v. Massachusetts*, where the plaintiff alleged that the state’s compulsory immunization law invaded his liberty because it was “hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best.”²⁷⁴ The Supreme Court rejected Jacobson’s claim, laying down the principle that municipalities may mandate immunizations without violating one’s constitutional liberty rights.²⁷⁵ Other state courts have followed suit, holding that school vaccination requirements do not deprive individuals of liberty or property interests without due process of the law.²⁷⁶ Additionally, courts have held that compulsory school vaccination laws are not an illegal search and seizure under the Fourth Amendment.²⁷⁷ Moreover, several courts have ruled that antivaccinationists’ arguments concerning the right to public education (absent government interference) do not prevent legislatures from imposing reasonable immunization laws on

270. See Wolfe et al., *supra* note 22, at 3247 (noting that 77% of antivaccination websites raise this concern).

271. See *id.* These registries seek primarily to monitor the safety of vaccines and to record any adverse events.

272. See Hodge & Gostin, *supra* note 26, at 849.

273. See *id.*

274. See *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905). Even before *Jacobson*, courts were called on to respond to the argument that compelling people to become vaccinated violates their individual liberty. See, e.g., *Blue v. Beach*, 56 N.E. 89, 91 (Ind. 1900) (holding that the state’s ability to compel vaccinations does not depend upon a consideration of whether it is an “outrage upon personal liberty” because it is justified as a public emergency); *Viemeister v. White*, 84 N.Y.S. 712, 714 (1903) (stating that the state’s vaccination law fell within the legislature’s power to make general laws because it did not violate the fixed limits past which the state cannot encroach on individual rights).

275. See *Jacobson*, 197 U.S. at 25–30.

276. See *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 885 (Ark. 1951) (featuring parents who argued that Arkansas’ law requiring children to be vaccinated denied them equal protection of the law and was “so arbitrary, capricious and unreasonable that its enforcement against the said plaintiffs would amount to a deprivation of their liberty and property without due process of law, contrary to [the Fourteenth Amendment]”).

277. See *McSween v. Bd. of Sch. Trs.*, 129 S.W. 206, 207–08 (Tex. Civ. App. 1910) (compulsory vaccination not in violation of Texas’ Constitution).

their citizens.²⁷⁸ Finally, while Americans do have the First Amendment right to be free from state infringement on their personal religious *beliefs*, the state can interfere with religious *practice* where it has harmful effects on the community.²⁷⁹

Thus, while personal freedoms are at the foundation of the American spirit and drive vaccination opponents, the judicial system has generally allowed those liberties to be limited when public health is at stake.

C. Information Versus Misinformation

Frightening information concerning vaccine safety and risks is becoming commonplace in America today. Anecdotal reports of vaccine-related harms that have affected particular individuals can quickly lead to tall tales and myths about immunization safety.²⁸⁰ Some of the most prevalent claims include:

1. Vaccines can overwhelm an infant's immune system
2. Vaccines erode immunity
3. Vaccine immunity is temporary and ineffective
4. Diseases have declined without immunizations

278. See *Viemester*, 84 N.Y.S. at 713–14, 716 (holding that because no constitutional right to an education exists in New York's Constitution, there is no limit on the type of reasonable vaccination requirement that may be imposed on public education by the legislature). See also *Maricopa County Health Dep't v. Harmon*, 750 P.2d 1364 (Ariz. 1987). The parents in *Maricopa* argued that the Arizona law excluding unimmunized children from schools "violated their fundamental constitutional right to privacy and their first amendment right to free exercise of religion." *Maricopa*, 750 P.2d at 1370. The parents specifically argued that because the policy of the state was to "balance the individual's right to education against the state's need to protect against the spread of infectious and contagious diseases," the state could not exclude children unless there were confirmed cases of measles at their particular school. *Id.* However, the court ruled that the state health department had the authority to exclude the unvaccinated children from school without violating their constitutional rights. *Id.*

279. See *Oregon Dep't of Human Res. v. Smith*, 494 U.S. 872, 890 (1990) (holding that state can outlaw use of peyote, even when used in religious context by Native Americans, because the Constitution does not protect all acts that may have a religious element); *Matter of Sampson*, 29 N.Y.2d 900, 901 (N.Y. 1972) (holding that even where parent has sincere religious belief opposed to life-saving blood transfusion, it must yield to State's *parens patriae* interest in protecting the life of innocent children). Moreover, courts have rejected plaintiffs' claims that the constitutional right to privacy protects immunization decisions. See *Hanzel v. Arter*, 625 F. Supp. 1259, 1262 (S.D. Ohio 1985) (rejecting plaintiff's analogy that the decision not to become immunized is no different than the decision whether or not to bear a child or to terminate a pregnancy, because contraception, abortion and vaccination all involve intrusion in the human body).

280. See *Maldonado*, *supra* note 198, at 3156.

5. Homeopathy is a viable alternative to vaccination
6. "Hot lots" of vaccines have more adverse events
7. Giving multiple simultaneous vaccines increases risk
8. U.S. vaccination policy is motivated by profit
9. Cell cultures from aborted fetal tissue are used to grow vaccine viruses.²⁸¹

As if the above contentions were not upsetting enough, the claims regarding diseases and disorders that vaccines directly *cause* are even more disturbing. Antivaccinationists contend that immunizations cause autism, multiple sclerosis, diabetes, SIDS, bacterial infections, and allergies. Given these shocking allegations, it is no wonder why parents might opt out of vaccinating their children.

Many of these alarming claims trace their roots to the use of thimerosal, an ethylmercury-based preservative present in vaccines for many years. Mercury is a known neurotoxin that in large quantities can cause motor symptom abnormalities that bear resemblance to those exhibited by autistic children.²⁸² While thimerosal has been utilized in vaccines since the 1930s, American infants have been exposed to greater levels of ethylmercury as the number of vaccines given to children has increased in recent decades.²⁸³ Simultaneously, the incidence of autism cases has dramatically risen in the last ten to twenty years.²⁸⁴ Typically, symptoms of autism begin to appear in a child's second year of life, about the same time that she has had a series of vaccines containing thimerosal.²⁸⁵ Antivaccinationists claim this correlation is no coincidence.²⁸⁶

281. See Wolfe et al., *supra* note 22, at 3246–47.

282. See Brody, *supra* note 260. Ethylmercury poisoning can trigger motor symptoms such as lack of coordination, unsteadiness, difficulty speaking because of poor muscle control, tremors, muscle pain, weakness, and spasticity. However, the only common motor symptoms witnessed in autism are repetitive behaviors such as flapping, circling or rocking. See *id.*

283. See *id.* Vaccines available in recent decades include those that protect against *Haemophilus influenzae* type b (hib), hepatitis B, diphtheria, tetanus, and varicella.

284. See *id.* See also Sandra Blakeslee, *Increase in Autism Baffles Scientists*, N.Y. TIMES, Oct. 18, 2002, at A1 (describing the shocking rise of autism cases in California).

285. The chronicled association between autism and the MMR vaccine relates to the shot given at one year of age. The concern about the series of vaccines containing thimerosal is principally associated with vaccines given in the first six months of life. See E-mail from Dr. Edgar Marcuse, *supra* note 30.

286. See Rosie Waterhouse, *Autism 'Linked to Mercury Vaccine'*, SUNDAY TIMES (London), May 27, 2001, available at <http://www.whale.to/m/autism5.html> (detailing claims that mercury in vaccines may be causing the steep rise in autism cases in children around the world) (on file with the University of Michigan Journal of Law Reform).

These disturbing contentions are worsened by distrust of government medical programs in general. Skeptics contend that the government is in bed with the vaccine industry and that everybody is making money off of giving shots to children.²⁸⁷ Some allege that corporate greed leads vaccine manufacturers to cover up safety risks in order to boost profits. In fact, one parent interviewed considered well-baby care to be a “capitalist plot.”²⁸⁸ These cynics dismiss research indicating that vaccines do not overwhelm children’s immune systems or increase their vulnerability to infections or other diseases, arguing that many of the studies are paid for by the pharmaceutical companies themselves.²⁸⁹ The problem is particularly severe in communities of color, which for understandable historical reasons exhibit a mistrust of medical research of all kinds, including immunizations.²⁹⁰ Thus, communicating and distinguishing between accurate information and misinformation is particularly difficult.²⁹¹

287. See McNeil, *When Parents Say No*, *supra* note 6, at A12. See also EDUCATE YOURSELF website, available at <http://educate-yourself.org/vcd/> (an antivaccination website which opens with “. . . Don’t allow your child to go on the chopping block for these Liars and their profit margins. They aren’t working for you, they’re servants of the corporate elite/Illuminati and the Illuminati has a surreptitious population reduction agenda in place.”). However, pharmaceutical companies claim that vaccines are not large money-makers, and that the threat of litigation exposure has caused many to exit the market entirely. In fact, only five companies produce vaccines today, compared with 25 three decades ago. See *Preventative Medicine*, *supra* note 192.

288. See McNeil, *When Parents Say No*, *supra* note 6, at A12.

289. See Donald G. McNeil, Jr., *Study Finds Vaccine Doesn’t Lead to Child Bacterial Infections*, N.Y. TIMES, Feb. 20, 2003, at A21 [hereinafter McNeil, *Child Bacterial Infections*]. Groups in Britain and the U.S. were skeptical when British Public Health Laboratory Service researchers found there was no evidence that the MMR vaccine overloaded children’s immune systems or increased their vulnerability to bacteria infections because much of the study was paid for by vaccine manufacturers. Skeptics also argued that the study did not address their real concern: that the MMR vaccine overwhelms defenses against viruses and thereby makes infants more vulnerable to autism. U.S. vaccine experts responded that those concerns were scientifically unsound and that the study was indeed accurate. See also *In Reply (to Dr. David M. Abbey)*, 288 J. AM. MED. ASS’N 1718 (citing statistics evidencing U.K. citizens’ distrust of government).

290. See Linda Villarosa, *Despite Need for H.I.V. Vaccines, Fear Mutes Call for Volunteers*, N.Y. TIMES, May 27, 2003 at F5. Much of the distrust stems from the infamous Tuskegee study, where for 40 years black men with syphilis were not given necessary treatment by medical researchers who wanted to study the course of the disease. See *id.* However, opposition to government mandated vaccination is not just a problem facing minorities and the inner cities—high rates of nonvaccination are also witnessed in wealthy, well-educated populations, perhaps due to “overeducation” regarding immunization risks and misinformation obtained over the internet. Interview with Dr. Anastasia Deliganis, conducted Nov. 21, 2003 (transcript on file with author).

291. See Peter Davies, *Antivaccination Websites*, in *Letters to the Editor*, 288 J. AM. MED. ASS’N 1717 (2002) (describing the difficulty in communicating risks of nonvaccination to those that embrace individualism, New Age lifestyles and ideas, or an antiauthoritarian

• *The Truth*—Though a fierce debate rages, many of the contentions detailed above lack mainstream scientific support. Vaccines do not overwhelm an infant’s immune system; babies actually possess billions of immunologic cells that are more than capable of responding to millions of different viruses and bacteria.²⁹² In fact, vaccines are no more than a “raindrop in the ocean” of what an infant’s immune system encounters every day.²⁹³ Furthermore, vaccines do not erode, but rather create immunity where there once was none.²⁹⁴ The protection that results generally lasts forever, though some immunizations must be updated.²⁹⁵ Alternative homeopathic treatments are generally not a viable alternative to vaccines, at least if one wishes to avoid disease.²⁹⁶ Moreover, pharmaceutical companies contend that vaccines are far from a cash cow. In fact, vaccine prices are often not high enough to prevent manufacturers from exiting the market—only five companies produce vaccines today compared to twenty-five three decades ago.²⁹⁷

Far more prominent in the media are stories concerning the link between vaccines (and thimerosal) and the alarming rise in autism.²⁹⁸ A correlation between the increase in immunizations

stance, and recommending that the medical profession’s response be tailored to the particular philosophical framework from which the vaccine fears originate). See also Perez-Pena, *supra* note 67 (suggesting that reluctance to receive smallpox vaccination is related to distrust of the Bush administration). Overcoming distrust of government may prove even tougher outside of the United States, as many residents of India are refusing polio vaccination for fears that it is a government sponsored population-control program. See Waldman, *supra* note 147.

292. See VACCINE EDUCATION CENTER, *supra* note 18; Edgar Marcuse, *Protect Your Child and the Community: Immunize*, NORTHWEST BABY & CHILD, Jan. 2003, at 7 (reporting that 25% of parents believe too many vaccines can overwhelm babies).

293. See P.A. Offit, *Addressing Parents’ Concerns: Do Vaccines Weaken or Overwhelm the Infant’s Immune System?*, 109 PEDIATRICS 124 (2002).

294. See WASHINGTON DOH, FACTS ABOUT CHILDHOOD IMMUNIZATIONS, *supra* note 115.

295. For instance, the vaccine against tetanus requires updating later in life. See CENTERS FOR DISEASE CONTROL, RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR 2002–03, available at <http://www.cdc.gov/nip/recs/adult-schedule.pdf> (on file with the University of Michigan Journal of Law Reform). Other immunizations are recommended for certain adult populations at risk for various other diseases. It is possible that some immunity is lost over long periods of time against some diseases, most notably smallpox.

296. See McNeil, *When Parents Say No*, *supra* note 6, at A1 (while some parents interviewed prefer homeopathy to vaccines, their trust in alternative remedies has been disappointed by recurrent outbreaks of whooping cough in their communities).

297. See *Preventative Medicine*, *supra* note 192.

298. See generally *60 Minutes: MMR Vaccine*, *supra* note 23; Fox, *supra* note 23; Allen, *supra* note 258; Benjamin, *supra* note 258. It is true that the rise in autism has been dramatic. Before 1970, about 1 child in 2,000 reported autism or one of its milder forms. Today, the numbers range from 1 in 500 children to 1 in 150 reporting autism or one of its milder

given and the increase in childhood autism certainly exists, but the issue of causation is a much more difficult one to prove. While both sides of the debate offer up no shortage of evidence, the majority of medical research—including an exhaustive study just published by Anders Hviid in the *Journal of the American Medical Association*—suggests that vaccines are not responsible for the surge in autism in recent decades.²⁹⁹ The Institute of Medicine (IOM) of the National Academy of Sciences also concluded that “the vast majority of cases of autism cannot be caused by [the] MMR vaccine,” although the IOM did not absolutely rule out immunizations as a rare cause of autism.³⁰⁰ Other studies published in leading American and British medical journals analyzing the incidence of autism relative to the timing of the introduction of the measles vaccine have failed to demonstrate an association between

forms. Other possible causes for the increase in reported cases are environmental factors or better diagnosis. See Brody, *supra* note 260.

299. See Anders Hviid, *Association Between Thimerosal-Containing Vaccine and Autism*, 290 J. AM. MED. ASS'N 1763, 1765 (2003) (concluding after a lengthy study that there is “no evidence of an association between thimerosal-containing vaccine and autism in children”). Multiple studies have refuted a causal link between the MMR vaccine and autism. See AMERICAN ACADEMY OF PEDIATRICS, *STUDY FAILS TO SHOW A CONNECTION BETWEEN THIMEROSAL AND AUTISM* (2003), available at <http://www.aap.org/prof/thimaut-may03.htm> (on file with the University of Michigan Journal of Law Reform); B. Taylor et al., *Autism and Measles, Mumps and Rubella Vaccine: No Epidemiologic Evidence for a Causal Association*, 351 LANCET 2026 (1999); E. Fombonne & S. Chakrabarti, *No Evidence for a New Variant of Measles-Mumps-Rubella Induced Autism*, 108 PEDIATRICS e58 (2001); K.B. Nelson & M.L. Bauman, *Thimerosal and Autism?*, 111 PEDIATRICS 674 (2003). See also Brody, *supra* note 260 (summarizing the debate and “fear factors” surrounding autism and vaccines). Despite these studies, if thimerosal is shown in the future to have contributed to the rise in autism, that would make out a prima facie case for children who have been injured to be compensated. However, given that thimerosal is no longer used in routine childhood immunizations, any potential causal link would not be an argument for opting out of vaccination today.

On the other side of the debate, antivaccinationists point to several sources linking mercury poisoning to the symptoms some vaccinated children are now exhibiting as evidence that a vaccine-autism connection exists. See Allen, *supra* note 258; Benjamin, *supra* note 258; *Toxic Metal Clue to Autism*, *supra* note 258.

300. See CENTERS FOR DISEASE CONTROL, IOM REPORT, available at <http://www.cdc.gov/nip/news/iom-04-24.htm> (on file with the University of Michigan Journal of Law Reform). The report continued:

The Committee's conclusion means that MMR cannot explain the recent increasing trends in autism diagnoses. While the available information does not implicate MMR as a cause of individual cases of autism, the information is insufficient to totally exclude MMR as a cause of autism in rare instances. No epidemiological study or clinical trial can ever establish that a vaccine is absolutely safe or that a particular vaccine reaction never occurs.

the two.³⁰¹ Moreover, erring on the side of caution, vaccine manufacturers removed thimerosal from all routinely recommended immunizations three years ago³⁰²—yet data has not indicated a drop in autism in the last few years.³⁰³ If thimerosal is indeed the root of vaccine-related injury in the past few decades, then one would expect that its removal would lead directly and quickly to a stunning decline in autism cases. If data eventually shows this drop-off, that would make out a *prima facie* case for compensating victims—but not a case for discontinuing vaccination—because this potential safety issue has already been addressed by eliminating thimerosal.

Moreover, allegations abound regarding the connection between immunizations and multiple sclerosis, SIDS, diabetes, bacterial infections, seizures and asthma. Again, while many of these disorders are on the rise, it is not clear what factors are triggering the increase.³⁰⁴ Studies conducted by the IOM failed to support hypotheses that vaccines are associated with multiple scler-

301. See L. Dales et al., *Time Trends in Autism and in MMR Immunization Coverage in California*, 285 J. AM. MED. ASS'N 1183 (2001); H. Peltola et al., *No Evidence For Measles, Mumps and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-Year Prospective Study*, 351 LANCET 1327 (1998); Fombonne & Chakrabarti, *supra* note 299; B. Taylor et al., *Measles, Mumps, and Rubella Vaccination and Bowel Problems or Developmental Regression In Children With Autism: Population Study*, 324 BRIT. MED. J. 393 (2002); J.A. Kaye et al., *Measles, Mumps and Rubella Vaccine and Incidence of Autism Recorded by General Practitioners: a Time Trend Analysis*, 322 BRIT. MED. J. 460 (2001); K.M. Madsen et al., *A Population-based Study of Measles, Mumps, and Rubella Vaccination and Autism*, 347 NEW ENG. J. MED. 1477 (2002); C.P. Farrington et al., *MMR and Autism: Further Evidence Against a Causal Association*, 19 VACCINE 3632 (2001).

302. See Brody, *supra* note 260; VACCINE EDUCATION CENTER, *supra* note 18. Some vaccines still do contain minute amounts of thimerosal, but the maximum amount of ethylmercury that an infant may be exposed to from routine immunizations has been reduced from approximately 187.5 micrograms to less than 3 micrograms. See FOOD AND DRUG ADMINISTRATION, THIMEROSAL IN VACCINES: FREQUENTLY ASKED QUESTIONS, available at <http://www.fda.gov/cber/vaccine/thimfaq.htm#q4> (on file with the University of Michigan Journal of Law Reform). The MMR vaccine—the one most frequently claimed to cause autism—has never contained thimerosal.

303. It may take a few more years before enough data is available to determine the consequences of thimerosal's removal from vaccines. If a dramatic fall in autism cases does occur, that will serve as compelling evidence confirming antivaccinationists' fears. If not, then the health care professional must seek to identify other causes.

304. See Hodge & Gostin, *supra* note 26, at 887. The increasing incidence of diabetes, autism, asthma and a host of other medical conditions could just as easily be linked to changes in lifestyle, such as the rise in fast food diets, wireless communications, and computer usage. However, there is little scientific evidence to conclusively point to any of these factors. Other more benign explanations for the rise in autism cases include the fact that the definition for autism has changed (making it easier for kids to "fit" into the category), and the reality that schools now offer more educational services to autistic children (making a diagnosis of autism critical to receiving these services). See Lindsey Tanner, *Autism Cases Rise, But Reasons May Not Be Negative*, SEATTLE TIMES, July 16, 2003, at A3.

rosis, neurodevelopmental disorders, or immune dysfunction.³⁰⁵ The IOM also found no link between SIDS and immunizations.³⁰⁶ In addition, the increased rate of diabetes mellitus in children has been shown by Graves and colleagues not to be caused by vaccine antigens.³⁰⁷ Furthermore, British Public Health Laboratory Service researchers found no evidence that the MMR vaccine increases children's vulnerability to bacterial infections.³⁰⁸ Research findings produced by the American Lung Association and many others also confirm that the increased incidence of asthma in children today is not due to immunizations.³⁰⁹ A recent *New England Journal of Medicine* report found that children who suffered rare fever-related seizures after getting the DTaP and MMR vaccinations did not have an increased risk for subsequent seizures or neurodevelopmental learning disabilities.³¹⁰

Thus, while fears about vaccination abound, parents must be vigilant to sort the facts from the fiction. There are indeed legitimate risks to vaccination but the CDC imposes strict measures to minimize those dangers, record adverse reactions, and correct

305. See Maldonado, *supra* note 198, at 3156–57; see also CENTERS FOR DISEASE CONTROL, IMMUNIZATION SAFETY REVIEW: HEPATITIS B VACCINE AND DEMYELINATING NEUROLOGICAL DISORDERS, available at <http://www.cdc.gov/nip/news/iom-hepb-5-2002/iom.htm> (on file with the University of Michigan Journal of Law Reform).

306. See Donald G. McNeil, Jr., *Vaccines and Infant Deaths Are Not Linked, Study Says*, N.Y. TIMES, Mar. 13, 2003, at A22.

307. See P.M. Graves et al., *Lack of Association Between Early Childhood Immunizations and Beta-cell Autoimmunity*, 22 DIABETES CARE 1694 (1999); M. Karvonen et al., *Association Between Type 1 Diabetes and Haemophilus Influenzae Type B Vaccination: Birth Cohort Study*, 318 BRIT. MED. J. 1169 (1999).

308. See McNeil, *Child Bacterial Infections*, *supra* note 289 (citing to a study by British Public Health Laboratory Service while noting the lack of public acceptance of the results since it was partially funded by vaccine manufacturers).

309. See THE AMERICAN LUNG ASSOCIATION, THE SAFETY OF INACTIVATED INFLUENZA VACCINE IN ADULTS AND CHILDREN WITH ASTHMA, available at <http://content.nejm.org/cgi/content/abstract/345/21/1529> (on file with the University of Michigan Journal of Law Reform); F. Destefano et al., *Childhood Vaccinations and Risk of Asthma*, 21 PEDIATRIC INFECT. DISEASE J. 498 (2002); H.R. Anderson et al., *Immunization and Symptoms of Atopic Disease in Children: Results from the International Study of Asthma and Allergies in Childhood*, 91 AM. J. PUB. HEALTH 1126 (2001); P. Kramarz et al., *Does Influenza Vaccination Exacerbate Asthma? Analysis of a Large Cohort of Children with Asthma*, 9 ARCHIVES FAM. MED. 617 (2000).

310. See William E. Barlow et al., *The Risk of Seizures after Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine*, 345 NEW ENG. J. MED. 656 (2001). See also CENTERS FOR DISEASE CONTROL, FEBRILE SEIZURES AFTER MMR AND DTP VACCINATIONS, available at <http://www.cdc.gov/nip/issues/mmr-dtp/mmr-dtp.htm> (noting that DTaP and MMR vaccinations can temporarily increase the risk for fever-related (called "febrile") seizures in some children, but that the harm is not usually permanent) (on file with the University of Michigan Journal of Law Reform).

them where possible.³¹¹ It is crucial that parents be able to distinguish accurate risk information from that which is not supported by medical research.³¹²

D. The Internet Adds Fuel to the Fire

While the claims detailed above are alarming enough, the rise of the internet as a means for communicating medical information has generated increased fear and uncertainty regarding immunization safety. Last year, Robert Wolfe and colleagues published an eye-opening account of the content contained on a dozen antivaccination websites.³¹³ All of the webpages examined stated that vaccines cause illnesses themselves, including autism, SIDS, immune dysfunction, diabetes, neurologic disorders (seizures, brain damage, learning disabilities, and attention deficit disorder), and atopic disorders (allergic rhinitis, eczema, and asthma).³¹⁴ Over 90% reported that vaccines erode immunity, that adverse reactions

311. The CDC compiles a database of all adverse reactions to vaccines with the intention of seeking to prevent or minimize them in the future. In the few cases where certain vaccines were found to present unacceptable levels of risk, they have been removed from the market or altered to enhance safety. See VACCINE EDUCATION CENTER, *supra* note 18.

312. This is not at all meant to imply that there are no serious vaccine-related risks. To the contrary, the CDC website provides significant data regarding vaccine-related adverse events and immunization safety issues. See CENTERS FOR DISEASE CONTROL, OVERVIEW OF VACCINE SAFETY, available at <http://www.cdc.gov/nip/vacsafe/> (on file with the University of Michigan Journal of Law Reform). Immunization coverage in the U.S. can be found at the CDC website, available at <http://www.cdc.gov/nip/coverage/default.htm>, and a wealth of statistical data is available at the IMMUNOFACTS website, available at <http://www.immunofacts.com/statistical.html>.

313. See Wolfe et al., *supra* note 22. Wolfe's research confirmed an earlier study published by Laeth Nasir of the Department of Family Medicine at the University of Nebraska Medical Center.

Websites opposed to vaccination include: NATIONAL VACCINATION INFORMATION CENTER website, available at <http://www.909shot.com> (a nonprofit organization dedicated to disseminating information on the risk of vaccines); SAFEMINDS website, available at <http://www.safeminds.org/links.htm>; CONCERNED PARENTS FOR VACCINE SAFETY website, available at <http://home.sprynet.com/~gyrene>; NEXUS MAGAZINE website, available at <http://www.nexusmagazine.com/shakenbaby.html> (stating that shaken baby syndrome is caused by vaccines); EDUCATE-YOURSELF website, available at <http://www.educate-yourself.org/vcd> ("[T]he dangers of vaccinations to your child's long term health prospects and longevity itself far outweigh any potential benefits touted by the pharmaceutical industry for vaccines."); MERCOLA.COM website, available at http://www.mercola.com/article/vaccines/legally_avoid_shots.htm (providing information on "How to Legally Avoid Unwanted Immunizations" and stating that "nobody, anywhere or any time and under any circumstances has the right or power in this country to immunize you or your children against your will and conviction").

314. See Wolfe et al., *supra* note 22, at 3246-47.

are underreported, and that vaccination policy is motivated by profit.³¹⁵ A majority stated that homeopathy is a viable option to vaccination,³¹⁶ that vaccine immunity is temporary, and that diseases have declined on their own without vaccination.³¹⁷

Moreover, the design attributes of antivaccination websites added to concerns regarding immunization risks. Anecdotal, emotionally charged stories of children who had allegedly been killed or harmed by vaccines could be found on a majority of sites.³¹⁸ These personal accounts, often accompanied by heartbreaking pictures, encourage “false consensus bias”—the tendency to rely on personal experience rather than systematic, scientific evidence.³¹⁹ Additionally, all of the websites provided access to fellow antivaccination proponents, including links on how to legally avoid immunizations and links to lawyers who will help parents file claims against vaccine manufacturers.³²⁰

The problem is compounded by the fact that over 137 million American adults are now online,³²¹ and that 80% of those individuals use the internet to seek out health information.³²² Over half who have visited online health sites consider “almost all” or “most” of the health information reported to be credible.³²³ This is of particular concern since many of the claims made on antivaccination websites have not been peer-reviewed in published medical literature.³²⁴

In this environment, parents must exercise extreme caution regarding the vaccination information they find on the web, and make sure there is a scientific basis for the claims being asserted.

315. *See id.* at 3247.

316. *See id.* (listing claims which include that homeopathy can help fight diseases in the same way vaccines can and can help reduce post-vaccination reactions).

317. *See id.* (reasoning that diseases had started to decline due to better nutrition and hygiene prior to the advent of immunizations, and therefore, that the data promoting the achievements made possible by vaccines is exaggerated).

318. *See id.*

319. *See id.* While pictures abound of those harmed by vaccines, few images of people suffering from the diseases that vaccines prevent are posted.

320. *See id.*

321. *See id.* at 3245.

322. *See id.*

323. *See id.*

324. *See id.* at 3247.

E. Risk Overperception

In addition to the vaccine-safety fears that health officials must address, many of the benefits of vaccines are overshadowed by their *perceived* risks. As more children receive vaccines, the *total number* (not necessarily percentage) of real and perceived adverse events increases.³²⁵ Precisely because vaccines are so effective, the annual number of adverse events reported due to immunizations in recent years has been higher than the total number of vaccine-preventable diseases.³²⁶ Ironically, the success of immunization programs has led to proportionately greater concerns regarding vaccine safety today than worries about the illnesses that vaccines prevent.³²⁷

Given this backdrop, it is easy to understand how well-meaning parents can overestimate the legitimate risks that vaccines pose to their children. Little media attention is paid to the health achievements made possible by immunizations, but much is given to vaccine-related injuries because of their rarity and ability to shock parents and catch viewers' attention.³²⁸ A study of vaccine safety versus risk perception published by Yvonne Maldonado in the *Journal of the American Medical Association* found that misconceptions and overperceptions regarding vaccine risks are common in many communities.³²⁹ Her study found that one of the most "important misconceptions regarding vaccination is the perceived association of a variety of systemic adverse events linked to specific vaccines."³³⁰ With respect to the well-publicized concerns that vaccines cause autism, diabetes or multiple sclerosis, she states that the public's perceptions are "based on anecdotal reports or data

325. See Mootrey et al., *supra* note 70, at 18-1.

326. See *id.* at 18-1, 18-8, 18-12. Data from 1998 indicates that there were 7,484 cases of diphtheria, measles, mumps, pertussis, polio, rubella, CRS, tetanus and hib combined, compared to 11,411 reports of adverse events from the vaccines themselves. Furthermore, while over 11,000 adverse events were reported, it is essential to keep in mind that over 100 million doses of vaccines were distributed. Finally, the data excludes numbers for varicella or chicken pox, which continues to afflict millions of American children despite availability of vaccination.

327. See Maldonado, *supra* note 198, at 3155. See also Edwards, *supra* note 36 (discussing the perception that vaccine-related adverse events appear to be more common than the diseases themselves, and that warnings from the media regarding vaccine safety are disturbing to parents and may contribute to delay or refusal of immunizations).

328. See, e.g., Fox, *supra* note 23 (covering Congressman Dan Burton's call for an investigation into the link between autism and vaccines).

329. See Maldonado, *supra* note 198, at 3156.

330. See *id.*

... that [s]cientifically rigorous studies have refuted."³³¹ Unfortunately, recent efforts to improve vaccine safety have led to heightened awareness of the possible adverse effects.³³² Maldonado concluded that many individuals have a "poor perception of the real and continued risk of exposure and illness due to vaccine-preventable infections," and that it is becoming "difficult for public health practitioners to convey ... a sense of urgency regarding vaccination."³³³

Furthermore, as a psychological phenomenon, studies indicate that individuals systematically misperceive risk of all kinds. Kip Viscusi has shown that individuals consistently overreact to, and overperceive the risk from, low probability but high tragedy events.³³⁴ At the same time, people underperceive the risk of death from more common diseases.³³⁵ This phenomenon impacts the vaccination arena, as it is far more alarming for a parent to hear about 1 child (out of millions) dying after being given a vaccine than it is to hear about diseases that have killed millions of human beings in the past. For example, in Britain, overperception of the risk posed by the MMR vaccine has caused immunization rates there to drop to 85% nationally since 1998, despite the fact that local measles outbreaks continue to occur and claim far more lives than vaccines ever have.³³⁶

331. See *id.* at 3156–57. Given these alarming claims, it is easy to understand why parents might overperceive vaccination risks and decide not to immunize their children.

332. See *id.* at 3156.

333. See *id.* See also Ann Bostrom, *Vaccine Risk Communication: Lessons from Risk Perception, Decision Making and Environmental Risk Communication Research*, 8 *RISK* 173, 173–76 (1997). Bostrom describes the risk misperceptions surrounding vaccination safety and their implications for communicating dangers and benefits to parents. One interesting risk perception problem that vaccination encounters is that of "omission bias"—the perception that actions are riskier than inactions. Because getting immunized involves taking an affirmative action, it may be perceived as riskier than contracting a disease, which requires no action be taken.

334. See W. KIP VISCUSI ET AL., *ECONOMICS OF REGULATION AND ANTITRUST* 661–63 (2d ed. 1995). Viscusi notes that individuals overperceive the risk of extremely unlikely but highly tragic events such as tornados, floods, and even botulism poisoning, while at the same time underestimating the risk from far more prolific killers like cancer and heart disease. I should note that the public's misperception of risk is not always a sign of irrationality. To the extent that tragic events themselves are highly publicized without any mention of frequency statistics for those events, individuals might rationally attribute a greater risk to those events occurring than the actual risk. *Id.* at 663. It is thus incumbent upon the media and government to try to educate citizens as to frequency of risks so that publicity does not distort public perception beyond reality. See *id.* See also Calandrillo, *supra* note 194, at 1000–02.

335. See VISCUSI ET AL., *supra* note 334, at 661–63 (noting that individuals systematically discount the risk of death from heart disease or cancer).

336. See McNeil, *Child Bacterial Infections*, *supra* note 289. Britons' fear of the MMR vaccine was made worse by the fact that Prime Minister Tony Blair will not say publicly whether or not his son has been given the immunization.

Thus, the media and healthcare providers must act vigilantly to combat the public's overperception of vaccine-related risks. The choices of well-meaning parents may be altered if they continue to hear more accounts of adverse events from vaccination than they do stories of the achievements made possible by virtue of immunizations.

F. Lawsuits on the Rise

Not surprisingly, fears regarding vaccine risks affect the atmosphere for litigation against vaccine manufacturers. While injury due to vaccination is rare, it does occur, and victims deserve recompense. Vaccine safety and accompanying litigation first became a hot topic in the 1960s and 1970s when individuals who had been harmed by the polio or DPT vaccines filed several lawsuits.³³⁷ Some of the more notable cases in the history of vaccine-injury litigation follow.³³⁸

Gottsdanker v. Cutter Laboratories was the first major case seeking recovery for injury due to the Salk oral polio vaccine.³³⁹ Tragically, two children contracted poliomyelitis shortly after being given the inoculation manufactured by defendant Cutter Laboratories.³⁴⁰ Cutter did not dispute the issue of causation (i.e., that its vaccine caused the polio cases). Rather, it argued that it was not liable because it followed and passed all of the federal government's safety regulations in the manufacturing process.³⁴¹ However, the California Court of Appeals upheld jury verdicts in favor of the children on the ground that negligence need not be proven since the product was sold under a guarantee of purity—hence, the manufacturer should be liable for any personal injury which resulted.³⁴²

337. See Gary L. Freed et al., *Safety of Vaccinations: Miss America, the Media, and Public Health*, 276 J. AM. MED. ASS'N 1869 (1996). The DPT vaccine has since been replaced by the DTaP, the later of which is associated with fewer safety complications.

338. For a broader discussion of vaccine injury litigation, see W.J. Curran, *Influence of the Courts of Law on Biologicals Development, Regulations and Use*, in *Proceedings of the International Conference on the Role of the Individual and the Community in the Research, Development and Use of Biologicals*, in WORLD HEALTH ORGANIZATION BULLETIN (cited in Dudgeon et al., *supra* note 38, at 62). See also Edmund W. Kitch et al., *U.S. Law*, in VACCINES 1165 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

339. 182 Cal.App.2d 602, 6 Cal. Rptr. 320 (Cal. Ct. App. 1960).

340. See *id.* at 605.

341. See *id.* at 610–11.

342. See *id.* at 607, 611–12. The total award amounted to \$139,000 for the children and \$8,300 in special damages for the parents.

Subsequent holdings came down against vaccine manufacturers on “failure to warn” theories of liability. In *Davis v. Wyeth Laboratories*, a man developed polio and paralysis after being immunized with a Wyeth-manufactured vaccine.³⁴³ The court held the manufacturer strictly liable on the ground that it had a duty to warn consumers against the risks inherent in vaccination.³⁴⁴ A few years later, in *Reyes v. Wyeth Laboratories*,³⁴⁵ Wyeth again was found liable for paralytic poliomyelitis suffered by an eight-month-old even though her injuries were most likely due to wild poliovirus rather than the vaccine itself.³⁴⁶ The jury reasoned that Wyeth should be liable for failing to market its unavoidably unsafe product in such a way as to warn parents of the dangers—regardless of whether it actually caused the injury.³⁴⁷

Another prominent case in the development of vaccine-injury litigation is *Tinnerholm v. Parke Davis & Co.*,³⁴⁸ in which an infant developed severe medical problems after a single dose of vaccine containing antigens against diphtheria, tetanus, pertussis, and poliomyelitis.³⁴⁹ Her father sued the manufacturer, arguing that the preservative in the vaccine was unstable and at fault for his daughter’s injuries.³⁵⁰ Despite substantial scientific evidence that the preservative was not the culprit, the judge held that Parke Davis breached its implied warranty of merchantability and was therefore liable for negligence.³⁵¹

These cases are significant in that they opened up new and uncharted avenues of legal liability against vaccine manufacturers, dramatically impacting the subsequent introduction and development of vaccines. Courts massaged difficult causation issues

343. 399 F.2d 121 (9th Cir. 1968).

344. *See id.* at 130.

345. 498 F.2d 1264 (5th Cir. 1974).

346. *See id.* at 1271. The victim contracted paralytic poliomyelitis two weeks after she received a dose of Wyeth Laboratories’ oral polio vaccine, but it appeared her polio was not caused by the vaccine, but rather wild poliovirus. *See Dudgeon et al., supra* note 38, at 63.

347. *See Reyes*, 498 F.2d at 1276–77. Another prominent polio vaccine-injury case was *Griffin v. U.S.*, 351 F. Supp. 10 (E.D. Pa. 1972). Like *Davis* and *Reyes*, a woman contracted poliomyelitis after taking a dose of the live virus oral vaccine. She and her husband brought suit under Federal Tort Claims Act to recover for her permanent quadriplegia. The court held that the conduct of the Division of Biologic Standards amounted to negligence per se because it released a lot of live vaccine for public consumption after test results did not demonstrate that its neurovirulence met allowed standards. The total award was \$1,200,000. *See id.* at 37.

348. 285 F. Supp. 432 (S.D.N.Y. 1968).

349. *See id.* at 436. The infant victim developed hyperpyrexia, seizures, right-hand paralysis and mental retardation.

350. *See id.* at 444–45.

351. *See id.* at 446. The total award was over \$650,000. *See id.* at 454.

in order to find a way for children afflicted by disease to receive compensation, despite a lack of scientific evidence in some instances that the vaccine itself produced the injury.³⁵² Vaccine manufacturers quickly learned their lesson and threatened to halt production unless guaranteed indemnification by the federal government.³⁵³ As a result, vaccine shortages ensued, prices skyrocketed, and Congress was forced into action.

*G. Congress Responds: The National Childhood
Vaccine Injury Act of 1986*

With lawsuits and prices rising and vaccine supplies dwindling, Congress had no choice but to respond to the competing concerns of vaccine manufacturers and their victims.³⁵⁴ In order to ensure continued vaccine production, reduce manufacturers' exposure to liability, and provide compensation to those harmed, Congress passed the National Childhood Vaccine Injury Act in 1986.³⁵⁵ The theory behind government-based compensation for vaccine-related injuries was simple: the state uses its police power to require immunizations of all its citizens in order to fight terrible but preventable diseases. While millions of lives are saved or improved, a small percentage of individuals will inevitably suffer severe ad-

352. See Freed et al., *supra* note 337. However, one should not ignore the fact that there have also been a number of cases where plaintiffs suffered actual damages from vaccines, but have not been able to successfully bring suit. For example, in *Sheffield v. Eli Lilly & Co.*, 192 Cal. Rptr. 870, 887–89 (Cal. Ct. App. 1983), the court held that the plaintiff's suit failed in large part because there was no proof as to which manufacturer created the vaccine that caused the injury. Similarly, in *Shackil v. Lederle Laboratories*, 561 A.2d 511, 512 (N.J. 1989), plaintiffs were denied recovery because the manufacturer of the DPT vaccine could not be identified and the New Jersey Supreme Court refused to recognize market share liability as a substitute for showing causation-in-fact. See also U.S. DEP'T OF HEALTH & HUMAN SERVICES, NATIONAL VACCINE INJURY COMPENSATION PROGRAM: MONTHLY STATISTICS REPORT THROUGH MARCH 10, 1999, available at <http://www.hrsa.dhhs.gov/bhpr/vicp/monthly.htm> (listing a total of 1,493 compensated claims and 3,516 dismissed claims, though it is difficult to know whether all dismissed claims lacked merit) (on file with the University of Michigan Journal of Law Reform).

353. See Dudgeon et al., *supra* note 38, at 62–63.

354. See Freedman, *supra* note 244, at 98.

355. National Childhood Vaccine Injury Act of 1986, tit. III, § 311 (a). The avowed public policy behind the Act was to respond to concerns of vaccine manufacturers who had threatened to withdraw from the market due to fears of liability that might result from the infrequent but unavoidable injuries caused by vaccines. See Rabin, *supra* note 25, at 958. See also Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1860–1902 (1995) (detailing the delicate balancing act that the Vaccine Act struck, and recommending improvements for its future).

verse reactions to the immunizations. Therefore, the government should be strictly liable for damages suffered as a result of immunizations that it compelled in the name of promoting overall public health welfare.³⁵⁶

With this theory in mind, the National Childhood Vaccine Injury Act sought to (1) educate the public regarding vaccination, (2) monitor adverse reactions, and (3) compensate the few victims without bankrupting manufacturers. The legislation requires that all vaccine providers (i.e., generally pediatricians) give formal notice to patients and parents regarding available immunizations.³⁵⁷ This includes the use of standardized, easy-to-read vaccine information sheets (VIS's) that help ensure patients are aware of the major benefits and risks of vaccination.³⁵⁸ Further, in the interest of monitoring results, any complication or injury that results from immunization must be reported to the Vaccine Adverse Event Reporting System (VAERS).³⁵⁹ Finally, and most importantly for victims, the Act established a no-fault compensation mechanism for those who are harmed by vaccines to recover for their losses.³⁶⁰

The no-fault compensation mechanism was designed to allow fair recovery for injury, and is financed by an excise tax on each dose of vaccine disbursed.³⁶¹ A two-tier recovery system was created. First, plaintiffs must initially file their claim in federal court, where a special master is appointed to gather evidence and determine the award.³⁶² The victim must establish that she suffers from an injury listed in the "Vaccine Injury Table," and prove that the adverse reaction occurred within a designated time frame, also laid out in the Table.³⁶³ If she can meet these threshold burdens, a nearly

356. See Dudgeon et al., *supra* note 38, at 64 (describing the rationale behind the Act's compensation scheme).

357. Formal notification is required for the following vaccines: DTaP or components, measles, mumps, rubella vaccine (MMR) or components, *Haemophilus influenzae* type b vaccine, hepatitis B vaccine, varicella, and poliomyelitis vaccines. See Orenstein et al., *supra* note 203, at 1012.

358. See *id.*

359. See *id.* In order to track adverse events, vaccine providers are required to record the date, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine in the patient's medical record. All of the public health sector is responsible for ensuring safety of immunization programs—including surveillance and investigation of disease, outbreak control, promotion of immunization, and monitoring of adverse events. *Id.*

360. See *id.*

361. See 42 U.S.C. § 300aa-11(a).

362. See *id.* § 300aa-11(c).

363. See Rabin, *supra* note 25, at 959. Before the Act's injury guidelines, U.S. law still imposed liability on manufacturers if anything "untoward" resulted from their vaccines. See Dudgeon et al., *supra* note 38, at 65.

irrefutable presumption of liability is imposed.³⁶⁴ Unlimited compensation will be granted to cover actual medical expenses incurred, costs of rehabilitation and lost earnings.³⁶⁵ Discretionary damages for pain and suffering may be awarded, but are capped at \$250,000.³⁶⁶ While claimants must first proceed under the above no-fault approach, they also retain the option of rejecting the special master's award and seeking tort relief instead. However, there are a number of built-in disincentives to opting for tort relief. The Act allows an appropriate warning to provide a defense against liability, and adopts the "learned intermediary" doctrine, which requires the manufacturer only to provide adequate notice to the party administering the vaccination (i.e., the pediatrician, not the patient).³⁶⁷ The Act also prohibits punitive damages as long as the manufacturer complied with FDA guidelines.³⁶⁸ Between 1988 and 1999, a total of 5,717 claims were filed under the no-fault provisions of the Act; 4,969 have been adjudicated and 1,300 resolved in the petitioner's favor, and over \$1 billion has been disbursed to compensate victims of vaccine-related complications.³⁶⁹

The Act has been successful in insulating manufacturers from massive liability exposure, vaccine production and innovation has continued, and compensation for vaccine-related injuries has been provided (though certainly not in all cases).³⁷⁰ Lawmakers are continuously pressed to balance the competing interests involved as

364. See Rabin, *supra* note 25, at 959.

365. See 42 U.S.C. § 300aa-15(a).

366. See *id.*

367. See *id.* § 300aa-22(b), (c).

368. See *id.* §§ 300aa-15(d), 300aa-23(d).

369. See U.S. DEP'T OF HEALTH & HUMAN SERVICES, *supra* note 352. Despite the compensation granted to date, some observers feel that the Act has not fulfilled its promise. Of the 5,717 claims brought, only 1,300 petitioners were successful in attaining compensation, as more than two-thirds of all claims were ultimately dismissed. See Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 320 (1999). Critics feel that the "overwhelming authority of the special masters and the causation requirements of the Act have caused the majority of persons injured by vaccines to be denied compensation." *Id.* Other commentators believe that the apparent success of the Act may encourage the substitution of no-fault compensation plans in other areas of the law, such as tort-based consumer protection for both medical and nonmedical products. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59 (1999).

370. While the Act has tried valiantly to balance these competing interests, it is not a complete solution to the problem of ensuring widespread immunization coverage of American children. Furthermore, several commentators contest the overall "success" of the Act, and have recommended changes for the future. See Jaclyn Shoshana Levine, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology*, 4 B.U. J. SCI. & TECH. L. 9 (1998) (urging that Congress should critically reexamine the Act); Cantor, *supra* note 355, at 1896-1901 (recommending modifications to the Act).

manufacturers seek legislation that shields them from litigation and shortens relevant statutes of limitations, while plaintiffs seek to litigate cases in state court (with no liability caps) instead of under the Act's guidelines.³⁷¹ For the sake of public health, both sides must be dealt with objectively and nonpolitically; victims must be guaranteed fair compensation for injury and manufacturers must not be driven out of the market due to fears of mounting liability exposure.

H. Final Consequence: Legally Opting Out of Vaccination

Despite congressional action to ensure compensation, fears about vaccine risks as well as deeply rooted beliefs in freedom from government interference have led to the proliferation of legally sanctioned exemptions to compulsory vaccination laws today.³⁷²

371. See, e.g., Sheryl Gay Stolberg, *Republicans Press for Bill to Shield Vaccine Makers From Suits*, N.Y. TIMES, Apr. 9, 2003, at A8. The proposed legislation would overhaul the 1986 Act and prevent state court lawsuits from proceeding (outside of the Act's no-fault framework) against vaccine ingredients or additives. The current fear is that Eli Lilly could be potentially liable in state court actions for its thimerosal preservative because it is not technically a vaccine, but rather a vaccine additive. Quite controversially, a rider was attached to the Homeland Security Bill seeking to shield Lilly from this exposure. See Sara Fritz, *Autistic Children Face Lawsuit Limits*, ST. PETERSBURG TIMES, Nov. 16, 2002, at 1A.

The statute of limitations for claims made under the Act is governed by 42 U.S.C. § 300aa-16 (Limitations of Actions), and parents may feel forced to file claims before they know if there has been harm or before causation is proven by medial research.

372. State laws concerning vaccination exemptions are summarized in the following table:

STATE	STATUTORY SOURCE(S)	RELIGIOUS EXEMPTION	PHILOSOPHIC EXEMPTION
AL	Ala. Code § 16-30-1	§ 16-30-3	N
AK	Alaska Stat. § 14.30.125	§ 14.07.125	N
AZ	Ariz. Rev. Stat. Ann. § 15-872	§ 15-873	Y
AR	Ark. Code Ann. § 6-18-702	§ 6-18-702	N
CA	Cal. Health & Safety Code § 120325	§ 120365	Y
CO	Colo. Rev. Stat. § 25-4-902	§ 25-4-903	N
CT	Conn. Gen. Stat. § 10-204a	§ 10-204a	N
DE	Del. Code Ann. Tit. 14 § 131	§ 14-131	N
DC	D.C. Code Ann. § 31-501	§ 31-506	N
FL	Fla. Stat. Ann. § 232.032	§ 232.032	N
GA	Ga. Code Ann. § 20-2-771	§ 20-2-771	N
HI	Haw. Rev. Stat. § 302A-1154	§ 302A-1156	N
ID	Idaho Code § 39-4801	§ 39-4802	Y
IL	105 Ill. Comp. Stat. § 5/27-8.1	410 ILCS § 315/2	N
IN	Ind. Code Ann. § 20-8.1-7-9.5	§ 20-8.1-7-2	Y
IA	Iowa Code Ann. § 139.9	§ 139.9	N
KS	Kan. Stat. Ann. § 72-5209	§ 72-5209	N

Medically-indicated exemptions have long been available for the rare but legitimate cases where vaccines can be expected to pose unreasonable risk to immuno-compromised children.³⁷³ However, the rise of religious and philosophical opt-outs has caused the American Medical Association to be concerned, and it has gone on record opposing both.³⁷⁴ At their foundation, religious and philosophical exemptions reflect a political and judicial attempt to reconcile competing personal and public interests.³⁷⁵ While most reasonably-minded physicians and health care professionals re-

KY	Ky. Rev. Stat. Ann. § 214.034	§ 214.036	N
LA	La. Rev. Stat. Ann. § 17:170(A)	§ 17:170(E)	Y
ME	Me. Rev. Stat. Ann. tit. 20-A § 6355	tit. 20-A § 6355	Y
MD	Md. Code Ann. Educ. § 7-403	§ 7-403	N
MA	Mass. Gen. Laws ch.76, § 15	ch.76, § 15	N
MI	Mich. Comp. Laws Ann. § 333.9208	§ 333.9215	Y
MN	Minn. Stat. Ann. § 121A-15	§ 121A.15	Y
MS	Miss. Code Ann. § 41-23-37	N	N
MO	Mo. Rev. Stat. § 167.181	§ 167.181	N
MT	Mont. Code Ann. § 20-5-403	§ 20-5-405	N
NE	Neb. Rev. Stat. Ann. § 79-217	§ 79-220	Y
NV	Nev. Rev. Stat. § 392.435	§ 392.437	N
NH	N.H. Rev. Stat. Ann. § 141-C:20-a	§ 141-C:20-c	N
NJ	N.J. Stat. Ann. § 26:1A-9	§ 26:1A-9	N
NM	N.M. Stat. Ann. § 24-5-1	§ 24-5-2dd	N
NY	N.Y. Pub. Health Law § 2164	§ 2164	N
NC	N.C. Gen. Stat. § 130A-155	§ 130A-157	N
ND	N.D. Cent. Code § 23-07-17.1	§ 23-07-17.1	Y
OH	Ohio Rev. Code Ann. § 3313.671	§ 3313.671	Y
OK	Okla. Stat. Ann. tit. 70, § 1210.191	§ 1210.192	Y
OR	Or. Rev. Stat. § 433.267	§ 433.267	N
PA	21 Pa. Cons. Stat. Ann. § 13-1303a	§ 13-1303a	N
RI	R.I. Gen. Laws § 16-38-2	§ 16-38-2	N
SC	S.C. Code Ann. § 44-29-180	§ 44-29-180	N
SD	S.D. Codified Laws § 13-28-7.1	§ 13-28-7.1	N
TN	Tenn. Code Ann. § 49-6-5001	§ 49-6-5001	N
TX	Tex. Code Ann. § 38.001	§ 38.001	N
UT	Utah Code Ann. § 53A-11-301	§ 53A-11-302	N
VT	Vt. Stat. Ann. tit. 18, § 1121	§ 1122	Y
VA	Va. Code Ann. § 22.1-271.2	§ 22.1-271.2	N
WA	WA Rev. Code Ann. § 28A.210.080	§ 28A.210.080	Y
WV	W. Va. Code § 16-3-4	N	N
WI	Wis. Stat. Ann. § 252.04	§ 252.04	Y
WY	Wyo. Stat. Ann. § 21-4-309	§ 21-4-309	N

See Hodge & Gostin, *supra* note 26, at 869-72 tbl. 2.

373. Medical exemptions may also be granted where the child is likely to suffer from a serious allergic reaction to the vaccine. In both the immuno-compromised and allergic cases, the risks of immunization outweigh the benefits. Few healthcare providers would favor vaccination in such instances.

374. See McNeil, *Worship Optional*, *supra* note 4, at D4.

375. See Hodge & Gostin, *supra* note 26, at 873.

spect parents' deeply held beliefs about how to best raise their children, nearly all fear the rise of "exemptions of convenience." These exemptions are so-named because they merely require that a parent check a box opting out her child out from vaccination so that she can attend school. They often occur at the last minute, when it is easier to mark the box than it is to complete the ACIP childhood immunization schedule. Certainly, most fair-minded people agree that an issue as important as vaccination should not be decided in haste and certainly not on the basis of expediency or convenience.

1. *Medical Exemptions*—All fifty states understandably allow for medical exemptions to immunizations.³⁷⁶ Generally, children who are immuno-compromised, suffer from certain forms of cancer, or who are allergic to vaccines qualify.³⁷⁷ A physician's signature is required, but one court has held that the state cannot force a child to provide a reason for a medical contraindication in order to receive a medical exemption.³⁷⁸

Medical exemptions, where verified by a physician as legitimately indicated, make sense. A child who will suffer more harm than good from immunization because of her unique, compromised health situation should not be vaccinated.³⁷⁹ It is important to recognize, however, that this form of opt-out occurs in exceptional cases only.

2. *Religious Exemptions*—Religious exemptions, on the other hand, do not present a medically necessary reason for abandoning vaccination. 48 states now allow opt-outs for religious reasons, and only 21 of those have ever denied a claim for one.³⁸⁰ The two states which have not yet been swayed by religious objectors to immunizations are Mississippi and West Virginia.³⁸¹

New York Times reporter Donald McNeil, Jr., in a story entitled *Worship Optional*, detailed the consequences of the rise in religious

376. See Alan R. Hinman et al., *Childhood Immunization: Laws that Work*, 30 J.L. MED. & ETHICS 122, 124 (2002).

377. See *id.*

378. See Jones ex rel. Jones v. State, Dep't of Health, 18 P.3d 1189, 1195 (Wyo. 2001).

379. Children who qualify would be placed in great jeopardy by vaccination, due to HIV or cancer status for instance.

380. See McNeil, *Worship Optional*, *supra* note 4, at D4. McNeil reports that 47 states allow such exemptions (Arkansas, West Virginia, and Mississippi being the exceptions), but as of 2000, the number was 48. See *supra* note 226 (discussing Arkansas' recent exemption provision). However, subsequent cases have challenged the constitutionality of such a strict exemption rule. *Id.*

381. See McNeil, *Worship Optional*, *supra* note 4, at D4.

exemptions to compulsory vaccination laws.³⁸² A variety of faiths have sprung up to enable parents to avoid vaccination on religious grounds, including the Congregation of Universal Wisdom, founded by New Jersey chiropractor Walter Schilling.³⁸³ The Church will provide parents seeking to avoid compulsory immunization the necessary documentation to qualify, as its tenets hold that “the laying on of hands to the vertebrae shall be the sole means of maintaining the life force,” and that “[n]o member of the Congregation shall have injected . . . into the body any foreign materials of unhealthy or unnatural composition.”³⁸⁴ This religion has made it possible for over 5,000 members in 28 states to attain legally valid exemptions to vaccination.³⁸⁵ When asked how he would feel if one of his followers contracted polio, Schilling’s reply was:

If they’re clear spinally, if the communication between God and the body is clear and they’re working at 100 percent efficiency, then their resistance will be higher. Unless God wants them to leave. God does want people to leave eventually. I wouldn’t feel I’d made a mistake. I’d feel it was part of God’s will.³⁸⁶

While cases like this make for interesting if not shocking reading, what does the law actually say about the legal requirements to qualify for a religious exemption to compulsory vaccination? Courts have logically held that one’s reason for seeking the exemption must be based on religious, not secular, grounds.³⁸⁷ Therefore, merely personal reasons for resisting immunization do not constitute a legitimate basis for religious exemption.³⁸⁸ For example, a parent’s sincerely held belief that immunization was contrary to “nature’s genetic blueprint” was found to be a secular justification not warranting exemption. However, many members of Amish

382. *See id.*

383. *See id.*

384. *Id.*

385. *See id.*

386. *See id.*

387. *Mason v. Gen. Brown Cent. Sch. Dist.*, 851 F.2d 47, 53 (2d Cir. 1988).

388. *Farina v. Bd. of Educ.*, 116 F. Supp. 2d 503, 508 (S.D.N.Y. 2000) (holding that Catholic parents’ beliefs regarding vaccinations were personal and medical and therefore not adequate basis to recover damages from the Board of Education based on its refusal to accept their religious exemption). However, an exemption claimed by a Jewish parent was allowed even though her religion does not object to vaccination. *See Berg v. Glen Cove City Sch. Dist.*, 853 F. Supp. 651, 655 (E.D.N.Y. 1994).

communities and followers of Christian Science have received legally valid religious exemptions to compulsory vaccination laws.³⁸⁹ Unfortunately, nearly every major outbreak of vaccine-preventable diseases in the last 25 years has occurred among members of those denominations.³⁹⁰

Another tricky legal issue to navigate in states that allow religious exemptions is determining which denominations qualify. For instance, do only "nationally recognized" churches count, or does any religious belief entitle a parent to an exemption for her child? A court in Kentucky has ruled that a requirement that parents be members of a nationally recognized and established church to qualify for exemption does not violate the Establishment Clause,³⁹¹ but it stands in the minority on this point. Several other state courts have concluded that once religious exemptions are allowed by state law, they must be granted to everyone and anyone who claims a "sincerely held religious belief" opposed to vaccination—and not just those emanating from officially recognized religions.³⁹² Unfortunately, states rarely enforce the "sincerely held" language,

389. See *Maier v. Besser*, 341 N.Y.S.2d 411, 413 (N.Y. Sup. Ct. 1972) (holding that the child of a parent who is bona fide Christian Scientist may be enrolled into school under statutory exemption from requirements for certificate of immunization). However, it is not just Christian Scientists or members of the Amish who have been granted religious exemptions to vaccination—even Jewish parents have qualified for religious opt outs despite the fact that Judaism does not prohibit vaccination. See *Berg*, 853 F. Supp. at 655.

390. The most recent American polio outbreaks occurred in Amish and Mennonite communities in 1979 and in a Christian Science school in 1972. Further, measles infected 125 students and killed three in a Christian Science school in Illinois in 1985, and afflicted Amish communities in 1987 and 1988, killing two. Rubella also took its toll on Amish areas in 1991, infecting close to 900 children and leaving dozens permanently deformed. See McNeil, *Worship Optional*, *supra* note 4, at D4. Numerous measles cases and deaths during the 1989 to 1991 American epidemic were attributed to religious objections to vaccination. See, e.g., Erich Smith, *Philadelphia Fights the Measles: Medicine-Shunning Churches Hit Hard*, HARRISBURG EVENING NEWS, Feb. 20, 1991, at A1; *Measles Kills Five Children in Philadelphia: Fundamentalists Rejected Inoculation*, KANSAS CITY STAR, Feb. 16, 1991, at A3.

391. *Kleid v. Bd. of Educ.*, 406 F. Supp. 902, 904 (W.D. Ky. 1976).

392. *Dalli v. Bd. of Educ.*, 267 N.E.2d 219, 222-23 (Mass. 1971) (holding that the state exemption for objectors who believe in the "tenets and practices of a recognized church of religious denomination" violates the Equal Protection Clause by giving preferential treatment to certain groups ("recognized churches and religious denominations") over others who have sincere, though unrecognized, religious objections); *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 87-88 (E.D.N.Y. 1987) (holding that a requirement that parents be "bona fide members of a recognized religious organization" to be exempt on religious grounds from school vaccination requirements violates the Establishment Clause); *Bowden v. Iona Grammar Sch.*, 726 N.Y.S.2d 685, 686-87 (App. Div. 2001) (holding that parents who followed the practices of Temple of the Healing Spirit were entitled to a religious exemption to vaccination requirements for their child because the state statute did not qualify which religions were eligible); *In re LePage*, 18 P.3d 1177, 1180 (Wyo. 2001) (holding that the Department of Health cannot inquire into sincerity of mother's religious beliefs in seeking exemption from vaccination laws).

instead routinely granting exemptions without verification.³⁹³ Worse, some courts have expressly *prohibited* their respective state health departments from inquiring into the sincerity of a parent's religious objection to vaccination.³⁹⁴

Given this reality, religious objections to compulsory vaccination laws are increasing rapidly.³⁹⁵ State legislatures and health departments must be empowered to verify their sincerity in order to prevent them from becoming exemptions of convenience.

3. *Philosophical Exemptions*—Besides the proliferation of religious exemptions to vaccination, over a dozen states now allow personal or philosophical objections to mandatory immunization laws, with two others permitting such opt-outs in certain settings.³⁹⁶ Instead of restricting their exceptions to purely religious or spiritual beliefs, many of these states have sanctioned opt-outs for "moral, philosophical or other personal beliefs," while others allow objections based simply on "his or her [i.e., the parent's] beliefs."³⁹⁷ Usually, the relevant statutes require that these beliefs be sincerely held or exercised in good faith,³⁹⁸ though these provisions are seldom enforced.³⁹⁹

The insertion of both religious and philosophical exemptions into compulsory vaccination laws reflects the delicate balance that states face between protecting the public health and respecting people's freedom and individualism. In Idaho for instance, the legislature initially passed compulsory immunization requirements

393. See McNeil, *Worship Optional*, *supra* note 4, at D4. Very few states inquire into the sincerity of religious objections, and many of the states that allow such opt-outs have never denied one. See also Hinman et al., *supra* note 376, at 125 (pointing out that 32 of 48 states with religious or philosophic exemptions have never denied a single claim for one).

394. See *LePage*, 18 P.3d at 1180; *Dep't of Health v. Curry*, 722 So. 2d 874, 878 (Fla. Ct. App. 1998).

395. See McNeil, McNeil, *Worship Optional*, *supra* note 4, at D4.

396. See Hinman et al., *supra* note 376, at 124. The states that allow philosophical exemptions are: Arizona (Ariz. Rev. Stat. Ann. § 15-873 (West 1998)), California (Cal. Health & Safety Code § 120365 (Deering 1999)), Idaho (Idaho Code § 39-4802 (Michie 1998)); Louisiana (La. Rev. Stat. Ann. § 17:170(E) (West 1999)), Maine (Me. Rev. Stat. Ann. Tit. 20-A, § 6355 (West 1999)), Michigan (Mich. Comp. Laws Ann. § 333.9215 (West 1998)), Minnesota (Minn. Stat. § 121A.15 (1998)), Nebraska (Neb. Rev. Stat. § 79-221 (2000)), North Dakota (N.D. Cent. Code § 23-07-17.1 (1999)); Ohio (Ohio Rev. Code. Ann. § 3313.67.1 (Anderson 1998)), Oklahoma (Okla. Stat. Tit. 70, § 1210.192 (1998)), Vermont (Vt. Stat. Ann. Tit. 18, § 1122 (1999)), Washington (Wash. Rev. Code. § 28A.210.090 (1998)), and Wisconsin (Wis. Stat. Ann. § 252.04 (West 1998)). See Hodge & Gostin, *supra* note 26, at 869-74 tbl. 2.

397. See Hodge & Gostin, *supra* note 26, at 874 tbl. 2.

398. See *id.*

399. See Hinman et al., *supra* note 376, at 125 (pointing out that 32 of 48 states that allow religious or philosophical exemptions have never denied a single application for one).

that contained no philosophical exceptions.⁴⁰⁰ However, when it appeared that the law might be challenged by executive resolution, the state promulgated revised legislation allowing exemptions from state immunization laws on “other grounds”—in effect, providing a blanket exception.⁴⁰¹ Given Americans’ deep respect for individual freedom, absolutely mandatory immunization laws meet stiff resistance, and philosophical or personal exceptions are often carved out to satisfy certain constituents.

Unfortunately, the increase in religious and philosophical exemptions has the potential to produce serious consequences. Studies have shown that exempt children are 22 to 35 times more likely to contract measles than vaccinated children, and 6 times more likely to catch whooping cough.⁴⁰² Several disease outbreaks have occurred as the result of exemptions to vaccination, and are discussed *infra*, Part III.B.

4. *Exemptions of Convenience*—While sincerely held religious or philosophical objections to compulsory vaccination laws are one matter, it is quite another for parents to opt out their children from immunizations simply because it is easier to do so than to fulfill the state’s mandatory vaccination schedule.

Sadly, however, in states that allow religious or philosophical exemptions, parents may choose this route solely because it is more convenient to sign the waiver form than it is to get their children immunized.⁴⁰³ In Washington for example, the State Department of Health studied 236 elementary schools where 5% or more of the students were legally exempted from compulsory immunizations.⁴⁰⁴ The findings were alarming. While the state offers medical, philosophical and religious exemptions, 95% of the exemptions claimed at these schools were based on “personal beliefs” alone.⁴⁰⁵ Bruce Jancin reports that “many of them appeared to be a matter of convenience rather than exemptions borne of deeply held conviction.”⁴⁰⁶ California’s experience with vaccination exemptions affirms this fear. In schools with the greatest number of opt-outs,

400. See *id.* at 126.

401. See *id.* at 126–27.

402. See Hinman et al., *supra* note 376, at 125 (citing to D.R. Feikin et al., *Individual and Community Risks of Measles and Pertussis Associated With Personal Exemptions to Immunizations*, 284 J. AM. MED. ASS’N 3145–3150 (2000), and Daniel Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles*, 282 J. AM. MED. ASS’N 47–53 (1999)).

403. See Jancin, *supra* note 28.

404. See *id.*

405. See *id.*

406. See *id.*

there was some indication that “parents claimed exemptions because it was easier to do so than to go to the effort of finding [their child’s] immunization record.”⁴⁰⁷

Worse, schools are given financial incentives to allow these exemptions of convenience because they do not receive full government funding for students who are excluded from school because they failed to comply with the immunization laws.⁴⁰⁸ Dr. Edgar Marcuse, professor of pediatrics at University of Washington, noted that half of the 236 Washington schools surveyed used the exemption process as a means of ensuring more government funding.⁴⁰⁹ Simply put, schools are tempted to encourage parents to check the exemption box in order to avoid having that child—and the funds attached to her—excluded from the school.

Moreover, few states rigorously police religious and philosophical exemptions or insist on their sincerity in practice. In fact, a 1998 study found that 32 of the 48 states that currently permit such exemptions have *never* denied an application for one.⁴¹⁰ New York is one of the notable exceptions, as its Board of Education takes the position that no established religion formally forbids vaccination. Dr. Terry Marx, the Board’s chief physician, states openly that “many applications are bogus” and that she rejects them “if they’re based on quackery.”⁴¹¹ The state is one of just a handful that requires applicants to write detailed letters justifying their objections to prevent the spread of exemptions of convenience.

Thus, the ease with which exemptions are granted to immunization laws threatens to undermine their intent. Legislatures, courts, and school officials should ensure that all opt-outs are the product of serious deliberation, and that it is not easier to receive a last minute exemption for one’s child than it is to immunize her.

407. See Hinman et al., *supra* note 376, at 125.

408. See Jancin, *supra* note 28.

409. *Id.*

410. See Hinman et al., *supra* note 376, at 125.

411. See McNeil, *Worship Optional*, *supra* note 4, at D4. Another official, speaking against her supervisor’s advice, admits to assessing the sincerity of claims for religious exemptions. Unfortunately, other state supreme courts have recently held that officials cannot question the sincerity of a parent’s religious objection to vaccination. See *In re LePage*, 18 P.3d 1177, 1180 (Wyo. 2001).

III. THE CONSEQUENCES OF LEGALLY OPTING OUT

Many observers now believe that vaccinations are becoming a victim of their own success.⁴¹² Today's generation no longer fears vaccine-preventable diseases because mass immunizations have made the debilitating illnesses themselves so rare. Unfortunately, serious consequences will follow the proliferation of legally sanctioned exemptions to compulsory vaccinations.

A. Herd Immunity Threatened

Many antivaccinationists argue, "Who is the state to tell me what I must do with my (or my child's) body? If other parents vaccinate their kids, they will be protected, so why should you worry what I do with mine?" Other vaccine-opponents might feel, "If everyone else vaccinates, then I don't have to because their immunity protects me."

Because so much focus in America is placed on individualism, it is easy to lose sight of the *communal* benefits of vaccines. Not only does each person who receives an immunization benefit, but all those around her do as well—the classic positive externality.⁴¹³ As exemption rates increase, however, it is not merely the individuals opting out whose lives are endangered. Rather, the safety of the entire community is jeopardized when overall immunization rates fall below a critical threshold.⁴¹⁴

412. See Julia Sommerfeld, *Vaccination Rates in State Among Lowest in Nation*, SEATTLE TIMES, Aug. 17, 2003, at A1 (citing to Dr. Edgar Marcuse).

413. Positive externalities occur when the benefits of one person's action accrue not just to that individual, but to those surrounding her. However, because that individual reaps only the private benefits (and not the greater community benefits), she has less incentive than society desires to engage in the communally beneficial act. For a discussion of positive externalities in the context of public goods, see Steve P. Calandrillo, *Eminent Domain Economics: Should "Just Compensation" Be Abolished, and Would Takings Insurance Work Instead?*, 64 OHIO ST. L.J. 451, 464–65 (2003).

414. See Hinman et al., *supra* note 376, at 125 (pointing out that immunization rates are not static and arguing that we need to ensure a sufficient percentage of individuals make the decision to vaccinate). See also Marcuse, *supra* note 292 (noting that the immunizations protect not only the child receiving them, but the community at large). Marcuse is concerned that immunization rates are dropping rapidly in King County, Washington (home to Seattle). The percentage of county two-year olds who have received three basic vaccines (DTaP, polio, and MMR) has dropped from 86.7% in 1998 to 76.5% today. *Id.* (referring to National Immunization Survey data).

This idea is based on the concept of “herd immunity.”⁴¹⁵ Most vaccine-preventable diseases are transmitted from person to person. When a large percentage of a given population is immunized against a disease, that “herd community” serves as a protective barrier against the spread of infection to others in the group who are not immunized or whose immune systems are suppressed due to age or infirmity.⁴¹⁶ Because herd immunity occurs at a level below a 100% immunization rate,⁴¹⁷ it is not necessary for every single person in a community to be vaccinated. However, herd immunity can exist only if a sufficiently high proportion of the population is immunized such that the transmission of the disease is effectively interrupted.⁴¹⁸ Therefore, society cannot allow every one of its members (or even a sizeable minority) to rely on the indirect protection afforded by other vaccinated members of the herd—because then community protection unravels as all try to “free ride” off of the benevolent acts of others.⁴¹⁹

With this reasoning as a backdrop, compulsory vaccination laws were enacted to ensure that all in the population received immunizations, thereby serving the wider public good by creating a herd community capable of protecting the weak within its borders.⁴²⁰ This protection is crucial because inevitably there will be individuals in society who cannot be immunized due to HIV, cancer, pregnancy or other serious medical conditions. Additionally, it takes several years for infants and young children to complete the

415. For a broad discussion of herd immunity, see P.E.M. Fine, *Herd Immunity: History, Theory, Practice*, 15 EPIDEMIOLOG. REV. 265 (1993); J.P. Fox et al., *Herd Immunity: Basic Concept and Relevance to Public Health Immunization Practices*, 94 AM. J. EPIDEMIOLOG. 179 (1971).

416. See Orenstein et al., *supra* note 203, at 1006. Some vaccinations may lose effectiveness over time, and many individuals are not immunized because they were not vaccinated (i.e., because of medical, religious or philosophical reasons). See *id.*

417. See *id.*

418. See Hinman et al., *supra* note 376, at 125. The percentage of the population that must be vaccinated to provide herd immunity and interrupt disease progress varies depending on the infectiousness of the underlying agent. For poliomyelitis, officials estimate that 80% of the population must be immunized, while for measles the critical percentage is in excess of 90%. See *id.*

419. These parents avoid subjecting their children to the risk of a vaccine-related adverse event, but still benefit from the immunized herd community around them. For example, since there have been no cases of polio in the United States for over 20 years now, an individual might reasonably decide to forego immunization (and any chance of being injured by the vaccine itself), counting on the fact that the overall population's immunity will protect against the disease being spread to her (i.e., she still receives the benefit regardless of vaccination). State imposed immunization laws are therefore explicit attempts to provide for the wider public good, even though in any single individual's case, the small risk she undertakes might outweigh the marginal benefit. See Hodge & Gostin, *supra* note 26, at 876–77.

420. See *id.* at 877.

ACIP recommended childhood immunization schedule.⁴²¹ During this time, they count on the herd community to protect them from contracting serious illness. If an older sibling brings home a virus in the meantime because friends at school were not immunized, his little sister's life may be threatened.⁴²²

Antivaccinationists do not bear these negative externality costs or harms directly, and therefore may not take them into account in making their decision not to be immunized. Those who opt out of immunizations may unintentionally place those with weakened immune systems due to age or infirmity in harm's way. As others emulate the practice, vaccination levels drop across the population, threatening overall herd protection and allowing disease hot spots to emerge.⁴²³

B. Disease Hot Spots Emerge as Exemptions Rise

The decline of communal herd immunity is not a merely academic concern. Disease outbreaks have already occurred, killing hundreds and hospitalizing thousands more. "Hot spots" are cropping up in communities across the United States and the rest of the world as well. The rise of exemptions to compulsory vaccination laws threatens to undermine the public health achievements made possible by widespread immunizations.

At the outset, it is important to distinguish and explain the significance between nationwide versus local exemption rates. Despite the rise of exemptions to mandatory vaccination laws, nationwide

421. Generally, it takes up to two years to receive a series of 20 different immunization shots. See CDC, IMMUNIZATION SCHEDULE, *supra* note 85. Moreover, many children do not complete the immunization schedule until they are old enough to enter school.

422. Furthermore, it is a common scenario that a pre-schooler may have a mother who is pregnant with a younger sibling. Her fetus could suffer devastating effects if she were to be exposed to rubella for instance.

423. See Hinman et al., *supra* note 376, at 125–26; A. Allen, *Bucking the Herd*, ATLANTIC MONTHLY, Sept. 2002. One should note that nationwide vaccination rates remain quite high; it is the concentration of exemptions in certain areas that threatens herd immunity and leads to the rise of disease hot spots. See *infra* Part III.B. See also Lauran Neergaard, *CDC: Not Enough Kids are Getting Vaccinations*, SEATTLE TIMES, Aug. 1, 2003, at A2 (noting that while nationwide vaccination rates are relatively high, "coverage varies widely among states and major cities, with pockets of the country where far too few youngsters are up to date on their shots"). Large cities in particular fare poorly with respect to immunization coverage. For example, in Newark, New Jersey, only 57.5% of toddlers were up-to-date on their shots in 2002. See *id.*

immunization rates are still quite high overall.⁴²⁴ However, it is vital to look at opt-out rates in local communities because statewide or national numbers can hide areas where exemptions are dramatically higher than overall averages indicate,⁴²⁵ making it possible for disease pockets to spring up.⁴²⁶ For instance, even though 84% of schools in California boast exemption rates of less than 1%, 1 in 25 schools indicated that over 5% of their students had not received their required immunizations.⁴²⁷ Other hot spots have cropped up in Boulder, Colorado and in towns in Missouri and Massachusetts.⁴²⁸ Moreover, the National Immunization Survey reported that in King County, Washington (a major population center home to Seattle), 24% of two-year olds are not fully immunized with the three most basic vaccines available (DTaP, polio, and MMR).⁴²⁹

The clustering of exemptions in these hot spots can lead directly to disease.⁴³⁰ Religious exemptions to vaccination in Amish, Mennonite and Christian Science communities are responsible for the last two major outbreaks of polio in America.⁴³¹ During the resurgence of mumps that began in 1986, large outbreaks were for the most part confined to states that did not have comprehensive (i.e.,

424. See McNeil, *When Parents Say No*, *supra* note 6, at A1. Just 1% of America's school-aged population is legally exempted from vaccination. Seven states claim exemption rates above 1%, and 3 states (Michigan, Washington and Wisconsin) show that greater than 2% of their schoolchildren have legally opted out. See Hinman et al., *supra* note 376, at 125. See also Maggie Fox, *More U.S. Children Vaccinated Than Ever—Report*, REUTERS, July 31, 2003, available at http://story.news.yahoo.com/news?tmpl=story&cid=594&ncid=594&e=1&u=/nm/20030731/hl_nm/health_vaccines_dc (noting that while “more U.S. children are being immunized than ever before, holes remain that put babies and small children at risk of deadly disease”) (on file with the University of Michigan Journal of Law Reform).

425. See Jancin, *supra* note 28.

426. See Hinman et al., *supra* note 376, at 125; McNeil, *When Parents Say No*, *supra* note 6, at A1.

427. See Hinman et al., *supra* note 376, at 125. Worse, it appears that some of these parents had opted out of vaccination because it was easier to do so than to fulfill their child's mandatory immunization schedule. See *id.*

428. See McNeil, *When Parents Say No*, *supra* note 6, at A1.

429. See Marcuse, *supra* note 292. The immunization rate for those three vaccines fell from 86.7% in 1998 to just 76.5% in 2002, meaning nearly one in four children are not fully protected.

430. See T. May & R.D. Silverman, ‘Clustering of Exemptions’ as a Collective Action Threat to Herd Immunity, 21 VACCINE 1048 (2003) (stating that, “[g]iven the growing number of exemptions and the increasing visibility of the anti-vaccine movement, policy makers must be vigilant for dangerous clustering in order to avoid loss of herd immunity”).

431. See McNeil, *Worship Optional*, *supra* note 4, at D4. An important corollary to the outbreaks of polio among religious groups is that the disease did not spread outside these communities due to high immunization rates in the surrounding areas. Religious exemptions to vaccination are also responsible for many of the measles cases in the United States during the 1989 to 1991 epidemic. See Tamar Lewin, *Measles and Faith Combine in 5 Deaths in Philadelphia*, N.Y. TIMES, Feb. 16, 1991, at A5.

kindergarten through grade 12) vaccination laws.⁴³² Whooping cough outbreaks have occurred every year since 1995 on Vashon Island.⁴³³ Worse, pertussis cases have actually been *increasing* nationally since the early 1980s with peaks every three to four years.⁴³⁴ In 1991, lack of widespread immunizations in Amish areas resulted in 890 cases of rubella and over a dozen permanently deformed children.⁴³⁵

These examples are just drops in the ocean compared to the devastating American measles outbreak of 1989–91, which disproportionately affected urban areas and recent immigrants in Southern California who lacked sufficient immunization coverage.⁴³⁶ Measles cases had plummeted nationally after the vaccine became available in 1963, as the 400,000 individuals afflicted in 1962 had dropped to just over 1,000 per year by the mid-1980s.⁴³⁷ The incidence of measles was low even among *non-vaccinated* individuals so long as a sufficiently high percentage of the surrounding herd community was immunized.⁴³⁸ While nationwide measles vaccination rates among school-aged children appeared adequate, the level of immunization was as low as 50% among two-year old children in some black and Hispanic communities.⁴³⁹ A devastating measles epidemic resulted, afflicting primarily unvaccinated mi-

432. See Plotkin & Wharton, *supra* note 116, at 283. The number of reported mumps cases in the U.S. went from 152,209 in 1968 (one year after the licensure of the mumps vaccine) to 751 in 1996. However, there was a relative resurgence of mumps in the U.S. in 1986 to 1987, when 7,790 and 12,848 cases, respectively reported. During this resurgence, large outbreaks generally occurred in those states that did not require mumps vaccinations for school attendance for all grades. In fact, in 1986, the reported incidence of mumps was 14-fold higher in fifteen states that did not require mumps vaccination at all and twice as high for states that only required mumps vaccinations for children first entering school than for those states that had a comprehensive mumps vaccination requirements through all grades. See *id.* See also S.L. Cochi et al., *Perspectives on the Relative Resurgence of Mumps in the United States*, 142 AM. J. DIS. CHILD. 499 (1995).

433. See McNeil, *When Parents Say No*, *supra* note 6, at A12.

434. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16. From 1990–96, 57 Americans died from pertussis; 49 of these deaths occurred in children less than 6 months old. See *id.*

435. See McNeil, *Worship Optional*, *supra* note 4, at D4.

436. See *California Measles Epidemic Claims 17 Lives This Year*, WASH. POST, Nov. 7, 1989, at Z5.

437. See SCHNEIDER, *supra* note 17, at 138. By 1995, only 309 U.S. measles cases were reported. See Redd et al., *supra* note 111, at 246. Last year, there were a grand total of just 37 afflicted individuals in the U.S. See Ornstein, *supra* note 127.

438. See Redd et al., *supra* note 111, at 246 (discussing critical threshold percentages for measles vaccination, with some studies suggesting that elimination of measles in the U.S. requires vaccine coverage rates of 97 to 98%).

439. See E.R. Zell et al., *Low Vaccination Levels of U.S. Preschool and School-age Children. Retrospective Assessments of Vaccination Coverage, 1991–1992*, 271 J. AM. MED. ASS'N 833 (1994). See also SCHNEIDER, *supra* note 17, at 138.

nority children in urban areas, many in Los Angeles County.⁴⁴⁰ In total, over 50,000 children nationwide contracted measles and 11,000 hospital days were required for treatment.⁴⁴¹ 132 children died and over \$100 million in health care costs were incurred.⁴⁴² Other less devastating but still significant measles outbreaks occurred in an Illinois Christian Science school in 1985, and among Amish communities in 1987 and 1988.⁴⁴³ Exemptions to immunization on religious grounds played a large role.⁴⁴⁴

Elsewhere around the globe, countries with low vaccination rates continue to suffer from devastating disease outbreaks. In Russia, diphtheria cases jumped from 900 in 1989 to 50,000 in 1994 after a drop in immunization coverage.⁴⁴⁵ Japan and England witnessed a tenfold increase in hospitalizations and deaths after the pertussis vaccine was discontinued in their countries.⁴⁴⁶ Both South Korea

440. See *California Measles Epidemic Claims 17 Lives This Year*, *supra* note 436, at Z5. The epidemic was by no means confined to California, as urban areas with low vaccination rates across the country were hit hard. See, e.g., Robert Byrd, *Measles Hits Cities Hardest*, S.F. CHRON., May 29, 1991, at B3 (stating that "urban children are getting measles and dying in numbers unthinkable a few years ago and health experts have a simple explanation: [c]hildren are not getting vaccinated"); Byrd, *supra* note 1, at 11A.

441. See CENTERS FOR DISEASE CONTROL, U.S. DEP'T OF HEALTH & HUM. SERVICES, *Measles—United States, 1992, 42 MORBIDITY & MORTALITY WKLY. REP.* 378 (1993); NATIONAL VACCINE ADVISORY COMMITTEE, *The Measles Epidemic: The Problems, Barriers, and Recommendations*, 266 J. AM. MED. ASS'N 1547 (1991).

442. See IMMUNIZATION ACTION COALITION, *supra* note 16.

443. See McNeil, *Worship Optional*, *supra* note 4, at D4.

444. See R.W. Sutter et al., *Measles Among the Amish: A Comparative Study of Measles Severity in Primary and Secondary Cases in Households*, 163 J. INFECT. DISEASE 12 (1991); Thomas Novotny et al., *Measles Outbreaks in Religious Groups Exempt from Immunization Laws*, PUB. HEALTH REP. (1988) (discussing measles outbreaks among Christian Scientists in southwest Illinois and Colorado). In response to the 1989–91 measles epidemic, U.S. health officials made two major vaccination policy changes to combat future outbreaks. First, measles vaccination was markedly increased in preschool-aged children and second, a two-dose measles immunization schedule was adopted to ensure maximum efficaciousness. By 1996, the vaccination goal of 90% coverage among two-year olds had been met. No large-scale U.S. measles outbreaks have occurred since though the rest of the world has not been so lucky. See Redd et al., *supra* note 111, at 248. See also SCHNEIDER, *supra* note 17, at 138. In 1997, there were only 135 cases of measles in the U.S. *Id.* By 2002, that number had declined to 37, prompting health officials to proclaim that measles is nearing extinction in America. See Ornstein, *supra* note 127.

445. See SABIN VACCINE INSTITUTE, OPEN STATEMENT ON VACCINES, available at http://www.sabin.org/programs_open_vaccine.htm (on file with the University of Michigan Journal of Law Reform).

446. See Gangarosa et al., *supra* note 16 (finding that in eight countries where immunization coverage was reduced, the rate of pertussis surged 10 to 100 times compared to the rate in countries where vaccinations were continued). During the 1970s, widespread concerns about the safety of whooping cough vaccine led to plummeting immunization levels, and produced 100,000 cases of whooping cough and 36 deaths. Japan witnessed a dramatic decline in pertussis immunization from 1974 (80% coverage) to 1979 (just 20%), which

and Japan experienced major measles epidemics in recent years due to low vaccination rates.⁴⁴⁷ Europe has also not escaped the ravages of measles when immunization coverage has dropped, as evidenced by outbreaks in Sweden in the late 1990s.⁴⁴⁸

These disease hot spots will continue to emerge as long as exemptions to vaccination laws proliferate unchecked, putting children's health in danger. Further, individuals afflicted with vaccine-preventable diseases today find themselves in a particularly unfortunate state since few healthcare resources are dedicated to curing diseases that are easily preventable on the front end.

C. Global Travel Increases the Risk of Higher Exemption Rates

Another factor that cannot be ignored is the risk of disease transmission due to the increased amount of global travel into and out of the United States. Even if a disease is eliminated in one region of the globe, transmission of the agent is still possible due to the ease of international transportation today.⁴⁴⁹ While most diseases are well under control inside American borders, the same cannot be said for the rest of the world. Despite the proclaimed goal of worldwide measles eradication by 2000, we are nowhere close.⁴⁵⁰ Nearly a million deaths continue to be reported annually.⁴⁵¹

resulted in 13,000 cases and 41 deaths. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

447. See WASHINGTON STATE DEP'T OF HEALTH, MEASLES HEALTH ADVISORY FOR WASHINGTON RESIDENTS, TRAVELERS, available at http://www.doh.wa.gov/Publicat/2001_News/01-15.html (warning King County, Washington residents regarding the dangers posed by international travel given measles outbreaks abroad) (on file with the University of Michigan Journal of Law Reform). Approximately 40,000 cases were reported in South Korea between March, 2000 and December, 2001. Japan suffers from a more ongoing problem, as 30,000 cases per year have been reported for the last twenty years. See *id.*

448. See V. Jormanainen et al., *An Outbreak of Measles Among School-aged Children in One School and Spread Nationwide, Sweden, April-July, 1997*, in EUROPEAN PROGRAMME FOR INTERVENTION EPIDEMIOLOGY TRAINING, available at <http://www.epiet.org/seminar/1997/jormanainen.html> (on file with the University of Michigan Journal of Law Reform); Susan van den Hof et al., *Measles Outbreak in a Community with Very Low Vaccine Coverage, the Netherlands*, National Institute of Public Health and the Environment, Bilthoven, The Netherlands, 593 EMERGING INFECTIOUS DISEASES 7 (2001) (describing the 1999-2000 measles outbreak in the Netherlands).

449. See Orenstein et al., *supra* note 203, at 1006.

450. The World Health Organization estimates that 900,000 measles-related deaths occurred in developing countries in 1999. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

451. See *id.* Further, measles cases number in the tens of thousands each year in some Asian nations, prompting King County, Washington health officials to issue an international

Polio persists in parts of India and Africa, albeit in much smaller numbers.⁴⁵² Diphtheria is far from eradicated in the former Soviet Union—between 1990 and 1999, lack of coordinated vaccination programs in Russia and neighboring states produced 150,000 cases and 5,000 deaths due to diphtheria.⁴⁵³ Pertussis in both Japan and England returned with a vengeance after millions in those countries discontinued immunizations because of widespread fears regarding pertussis vaccine risks.⁴⁵⁴ In Japan, vaccination rates plummeted from 80% in 1974 to just 20% by 1979, producing 13,000 whooping cough cases and 41 deaths.⁴⁵⁵ The United Kingdom was hit with 100,000 cases and 36 deaths.⁴⁵⁶ In today's world, all of these life-threatening diseases are just a plane ride away.

In fact, this risk has already materialized. In 1998, *all* of the measles cases in the United States came from other countries.⁴⁵⁷ In 2001, measles was again introduced into Seattle by international travelers.⁴⁵⁸ More than half of the total number of measles cases reported by Americans that year were contracted by individuals in another country or were secondary-cases related to an imported case.⁴⁵⁹ While the Western Hemisphere has triumphed over polio, in 1994 wild polio virus was imported into Canada from India.⁴⁶⁰ From 1995–2000, 61 confirmed cholera cases hit Americans, the majority of which were imported from outside the United States.⁴⁶¹ Just two years ago, typhoid fever made a return to America, with

travel alert for Seattle-area residents in 2001. See News Release, Washington State Department of Health, Measles Health Advisory for Washington Residents, Travelers (Feb. 21, 2001), available at http://www.doh.wa.gov/publicat/2001_news/01-15.html (on file with the University of Michigan Journal of Law Reform).

452. See Allen, *supra* note 78. But see U.N. Says It Can Eradicate Polio by 2005, *supra* note 147 (indicating that polio could be defeated worldwide if currently afflicted nations gave full support to widespread immunization programs).

453. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

454. See Gangarosa et al., *supra* note 16.

455. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16.

456. See *id.*

457. See Marcuse, *supra* note 292.

458. See *id.*

459. See Maldonado, *supra* note 198, at 3156. See also *supra* note 449 and accompanying text. Furthermore, molecular epidemiologic studies indicated that the American measles outbreaks of 1996 and 1997 were most likely caused by importation of measles from abroad, most frequently from western Europe and Japan. See CENTERS FOR DISEASE CONTROL, PREVENTING EMERGING INFECTIOUS DISEASES: A STRATEGY FOR THE 21ST CENTURY, available at http://www.cdc.gov/ncidod/emergplan/plan_98.pdf (on file with the University of Michigan Journal of Law Reform).

460. See CDC, IF WE STOPPED VACCINATIONS, *supra* note 16. High vaccination levels in the Canadian population prevented the polio virus from spreading. See *id.*

461. See E.B. Steinberg et al., *Cholera in the United States, 1995–2000: Trends at the End of the Millennium*, 184 J. INFECT. DISEASE 799 (2001).

80% of cases occurring in individuals who reported traveling abroad in the six weeks prior to infection.⁴⁶² Finally, it is worth noting that HIV/AIDS could be added to the list of imported diseases, as experts believe the disease originated in Africa before being brought into the United States.⁴⁶³ The most recent infectious disease to spread its way into North America from abroad is Severe Acute Respiratory Syndrome—of the 64 U.S. cases at the time of writing, 97% have been attributed to international travel.⁴⁶⁴

D. The Financial Cost of Saying No to Vaccination

Vaccines are among the most cost-effective form of health care ever provided. Nevertheless, they continue to be underused worldwide, allowing preventable diseases to remain viable threats to our human and financial resources.⁴⁶⁵ The decision to opt out of vaccination therefore deals a serious monetary blow to our cash-strapped medical system.

For instance, the staggering bill for the U.S. measles outbreak between 1989–91 wound up topping \$100 million in direct medical costs, plus 44,000 hospital stays and countless lost work hours.⁴⁶⁶ Low vaccination rates against hepatitis B mean that approximately 12.5% of Americans will become infected at some point in their lifetime.⁴⁶⁷ About 5,000 of those individuals will die each year from hepatitis B-related liver disease, not to mention the \$700 million in medical and work loss costs incurred.⁴⁶⁸ Vaccines for poliomyelitis and congenital rubella have resulted in trillions of dollars in savings, and have helped prevent the inhumane suffering previously

462. See S.J. Olsen et al., *Outbreaks of Typhoid Fever in the United States, 1960–99*, EPIDEMIOLOG. INFECT. (2002). Malaria cases also attacked U.S. residents that same year, as not only did 1,544 cases occur, but twice as many cases occurred in Americans who had traveled outside of the country. See *Summary of Notifiable Diseases—United States, 2001*, *supra* note 97.

463. See CHARLES H. RUSSELL, AIDS IN AMERICA (1991); MIRKO D. GRMEK, HISTORY OF AIDS: EMERGENCE AND ORIGIN OF A MODERN PANDEMIC (Russell C. Maulitz & Jacalyn Duffin trans., 1990).

464. See CENTERS FOR DISEASE CONTROL, *Update: Severe Acute Respiratory Syndrome—United States*, 52 MORBIDITY & MORTALITY WKLY. REP. 436 (2003), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5219a2.htm>.

465. See J. Ehreth, *The Global Value of Vaccination*, 21 VACCINE 596 (2003).

466. See Washington DOH, *Childhood Immunizations*, *supra* note 3. See also *Measles—United States, 1992*, *supra* note 441; NAT'L VACCINE ADVISORY COMM'N, *The Measles Epidemic: The Problems, Barriers, and Recommendations*, 266 J. AM. MED. ASS'N 1547 (1991).

467. See CDC, *If We Stopped Vaccinations*, *supra* note 16.

468. See *id.*

endured by thousands of handicapped, paralyzed or deformed children.⁴⁶⁹ While some argue that continued polio vaccination is unnecessary since the disease is eradicated in the Western hemisphere, Khan and Ehreth contend that the future medical care cost savings from continued immunization (\$128 billion) will be almost double the actual financial expense of the vaccine itself (\$67 billion).⁴⁷⁰ In addition, they claim that pressing forward with vaccination instead of allowing complacency to set in will prevent 855,000 deaths, 4 million paralytic polio cases and 40 million disability adjusted life years between 1970–2050.⁴⁷¹

Moreover, European studies have found that low vaccination coverage against influenza resulted in over \$1 billion worth of total costs during Germany's 1996–97 flu epidemic, and almost \$2 billion in France during its 1989 outbreak.⁴⁷² U.S. studies have found that \$117 in healthcare costs per influenza vaccine are averted when individuals make the decision to be vaccinated instead of opting out.⁴⁷³ The financial impact of other vaccines is substantial as well, as Koplan has produced evidence over multiple studies regarding the cost-effectiveness of immunizations for diphtheria, tetanus, pertussis and measles.⁴⁷⁴ Finally, while vaccines save the lives of 3 million global citizens each year, it is estimated that 2 million more deaths (and their associated healthcare resource ramifications) could be avoided if the entire population had access to, and could afford, the vaccines that are currently available.⁴⁷⁵

Thus, while the decision not to vaccinate clearly implicates an individual's right to freedom of choice, it also has ramifications for societal human and financial resources. Unfortunately, vaccine-

469. See Dudgeon et al., *supra* note 38, at 61. See also CENTERS FOR PUBLIC HEALTH RESEARCH AND EVALUATION, *supra* note 196.

470. See M.M. Khan & J. Ehreth, *Costs and Benefits of Polio Eradication: A Long-Run Global Perspective*, 21 VACCINE 702 (2003) (discussing the financial impact of the decision whether to discontinue polio vaccination after 2010).

471. See *id.*

472. See WORLD HEALTH ORGANIZATION, INFLUENZA VACCINE, available at <http://www.who.int/vaccines/en/influenza.shtml> (on file with the University of Michigan Journal of Law Reform). Moreover, among nursing home residents, influenza vaccination reduces hospital stays (and the associated costs) by about 50%, the risk of pneumonia by 60% and the risk of death by 68%. See *id.*

473. See Riddiough et al., *supra* note 152; *Economic Analysis of Influenza Vaccination and Antiviral Treatment for Healthy Working Adults*, *supra* note 152 (finding that "vaccination is cost-beneficial in most influenza seasons). But *c.f.* Bridges et al., *supra* note 152 (raising questions about the net cost-benefit impact of influenza vaccine for healthy adults under 65).

474. See J.P. Koplan, *supra* note 197; J.P. Koplan & N.W. Axnick, *supra* note 197; J.P. Koplan et al., *supra* note 197; J.P. Koplan & C.C. White, *supra* note 197.

475. See F.E. Andre, *Vaccinology: Past Achievements, Present Roadblocks and Future Promises*, 21 VACCINE 593 (2003).

preventable diseases impose \$10 billion worth of healthcare costs and over 30,000 otherwise avoidable deaths in America each year.⁴⁷⁶

IV. PROPOSED SOLUTIONS

Many commentators argue that public health safety requires states to draw sensible limits on vaccination exemptions.⁴⁷⁷ In an effort to reduce exemptions of convenience, states should enact exemption processes that ensure careful deliberation by parents regarding immunization benefits and risks. At the same time, states should avoid imposing onerous hurdles that would thwart individual rights and freedoms. Some proposed solutions follow.

A. States May Limit Vaccination Exemptions

Given the potential harm that opting out of immunization imposes on children, state health departments and legislatures should consider providing legal frameworks that would prevent the proliferation of vaccination exemptions. Each state, relying on its *parens patriae* power, has a duty to ensure the well-being of its citizenry where the health and safety of innocent children is placed in jeopardy.⁴⁷⁸ The AMA has already gone on record indicating its opposition to both religious and philosophical exemptions to vaccination⁴⁷⁹—states might consider doing the same.

1. Religious Exemptions are Probably Not Constitutionally Required—Even though the great majority of states allow religious exemptions, they are probably not constitutionally required. While critics contend that prohibiting such opt-outs to vaccinations would

476. See Maldonado, *supra* note 198. As an aside, the financial toll on vaccine manufacturers has also been overwhelming, as lawsuits threatened to drive producers out of business until Congress passed the National Vaccine Injury Act of 1986 establishing no-fault compensation guidelines and capping non-economic damages at \$250,000. See generally Cantor, *supra* note 355.

477. See, e.g., Sommerfeld, *supra* note 412 (citing to Dr. Daniel Salmon, who notes that some states require no explanation for parents to receive vaccination exemptions for their children, while others require a notarized letter or another additional hurdle).

478. See, e.g., Troxel v. Granville, 530 U.S. 57, 88 (2000) (finding that a parent's interests in a child must be balanced against the State's long-recognized interests as *parens patriae* (citing Reno v. Flores, 507 U.S. 292, 303–304 (1993))).

479. See McNeil, *Worship Optional*, *supra* note 4, at D4 (noting that the AMA believes that religious and philosophical exemptions serve to increase the risk of disease epidemics).

interfere with freedom to worship and thus run contrary to the First Amendment's Free Exercise Clause, the Supreme Court has never rendered such a ruling.⁴⁸⁰ Rather, caselaw generally supports a state's right to limit religious objections if it so chooses.⁴⁸¹

In upholding New York's compulsory polio vaccination law, one court reasoned, "separation of church and State does not mean that every State action remotely connected with religion must be outlawed."⁴⁸² Furthermore, Mississippi excludes religious exemptions entirely, as its state Supreme Court found them in violation of the Equal Protection Clause on the ground that they "discriminate against the great majority of children whose parents have no such religious convictions" opposed to vaccination.⁴⁸³ An Arkansas court banned religious objections to vaccination as well, holding that the right of free exercise is subject to reasonable regulation for the good of the community as a whole.⁴⁸⁴

States interested in limiting religious exemptions to vaccinations might draw an analogy to high profile Jehovah's Witness cases, where advocates of religious freedom resisted laws compelling medical treatment in certain circumstances.⁴⁸⁵ Adherents of the religion have long believed that blood from one person should never be introduced into the body of another, under pain of loss of salvation for one's soul.⁴⁸⁶ Controversy erupted when parents who held these deep religious convictions refused blood transfusions for their children in emergency situations. Hospital staff sought to

480. See *supra* Part I.D.

481. *McCartney v. Austin*, 293 N.Y.S.2d 188, 200 (1968); *Cude v. State*, 377 S.W.2d 816, 818 (Ark. 1964); *Wright v. DeWitt Sch. Dist.*, 385 S.W.2d 644, 649 (Ark. 1965).

482. See *McCartney*, 293 N.Y.S.2d at 198. Further, in allowing religious freedom in America, that right "shall not be so construed as to excuse acts of licentiousness, or justify practices inconsistent with the peace or safety of this State." See *id.* at 199.

483. *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979).

484. See *supra* notes 224, 226 and accompanying text.

485. See *State v. Perricone*, 181 A.2d 751, 759-60 (N.J. 1962) (upholding forced blood transfusion against parents' religious beliefs based on the best interest of the child); *In re Clark*, 185 N.E.2d 128, 132 (Ohio 1962) (holding that the Ohio statute allowing court to summarily provide for emergency medical or surgical treatment for any child upon certificate of reputable practicing physician does not violate due process); *Jehovah's Witnesses v. King County Hosp. Unit*, 278 F. Supp. 488 (W.D. Wash. 1967), *aff'd* 390 U.S. 598 (1968) (upholding constitutionality of state statute allowing superior court to declare children to be dependent for purpose of authorizing blood transfusions to children against expressed objections of parents, based on *Prince v. Massachusetts*, 321 U.S. 158 (1944)); *In re Sampson*, 29 N.Y.2d 900, 901 (N.Y. 1972) (holding that a religious objection to blood transfusion does not present a bar to a Family Court order in neglect proceeding where the transfusion is necessary to the success of required surgery).

486. See JEHOVAH'S WITNESSES website, available at <http://www.bbje.org/WrestedScriptures/A05JW/Genesis9v4.html> (discussing the religion and noting that Jehovah's Witnesses cite to Genesis 9:4 as evidence that blood transfusions are forbidden by Scripture).

provide such treatment, knowing that childrens' lives hung in the balance. Jehovah's Witnesses challenged this "forced healthcare" practice as an unconstitutional violation of their religious freedom.⁴⁸⁷ In multiple cases, courts upheld the right of states to require blood transfusions in the best interests of the child despite the parents' adamant and sincere religion-based refusals.⁴⁸⁸ The New Jersey Supreme Court put it simply: "[W]hile freedom to believe is absolute, freedom to exercise one's belief is not and must be considered in light of the general public welfare."⁴⁸⁹ In the context of compulsory vaccination laws, the U.S. Supreme Court has unambiguously stated:

The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death. * * * Parents may be free to become martyrs themselves. But it does not follow [that] they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.⁴⁹⁰

487. See *supra* note 485; *Jehovah's Witness*, 278 F. Supp. at 488.

488. See *id.*

489. See *Perricone*, 181 A.2d at 756 (citing *McBride v. McCorkle*, 130 A.2d 881 (N.J. Super. Ct. App. Div. 1957)).

490. See *Prince*, 321 U.S. at 166-67. Other prominent Supreme Court cases confirm that the right to free exercise of religion is not absolute. See *Oregon Dep't of Human Res. v. Smith*, 494 U.S. 872, 885 (1990) (holding that the test for evaluating a Free Exercise claim when it comes up against a state statute that is of general applicability should be deferential to the state's exercise of its police power). Moreover, the Court cited to Supreme Court cases upholding compulsory vaccination as part of its justification. See *id.* at 905-06 (citing to *Jacobson's* denial of an exemption from smallpox vaccination laws). Other courts have held similarly in denying religious exemptions, stating, "[l]aws are made for the government of actions, and while they cannot interfere with mere religious belief and opinions, they may with practices." *Cude v. State*, 377 S.W.2d 816, 818 (Ark. 1964) (holding that parents do not have a legal right to prevent vaccination of children even if the parents' objections are based on good faith religious beliefs). The *Cude* court stated in relevant part:

According to the great weight of authority, it is within the police power of the State to require that school children be vaccinated against smallpox, and that such requirement does not violate the constitutional rights of anyone, on religious grounds or otherwise. In fact, this principle is so firmly settled that no extensive discussion is required. In the early case of *Reynolds v. United States*, 98 U.S. 145, 25 L.Ed. 244, the issue was whether a Mormon who believed in polygamy was immune from the operation of the statute forbidding the practice of multiple marriage. There, the court said: 'the only question which remains is, whether those who make polygamy a part of their religion are excepted from the operation of the statute. If they are, then those who do not make polygamy a part of their religious belief may be found guilty and punished, while those who do, must be acquitted and go free. This would be intro-

If the judiciary were to hold to the contrary, and the arguments of religious objectors were taken to their fullest extent, some courts have argued that absurd results would ensue. The *Cude* court rhetorically questioned, “[s]uppose one believed that human sacrifices were a necessary part of religious worship, would it be seriously contended that the civil government under which he lived could not interfere and prevent a sacrifice?”⁴⁹¹ While objections to mandatory vaccination laws clearly do not provide as an immediate or as certain of a risk of death or harm, it is clear that caselaw supports the notion that the public’s overall health and welfare trumps religious practices that threaten innocent citizens. A parent’s right to exhibit religious freedom ceases where it transgresses the rights of her innocent child.⁴⁹²

Thus, while the government cannot interfere with one’s religious beliefs, it can override one’s religious practice when the welfare of innocent parties is at stake. Some states may take the initiative to similarly limit the proliferation of religious exemptions to compulsory vaccination laws in the interest of protecting the children who reside within their borders.

2. *Philosophical Exemptions May Lead to Opt-Outs of Convenience*—While philosophical exemptions are certainly not constitutionally required, over a dozen states permit them today.⁴⁹³ These objections pose a risk to societal welfare because they allow parents to decline to vaccinate their children even where there is no documentation of a sincere belief opposed to immunization. In practice, the availability of philosophical exemptions often results in “exemptions of convenience”—parents opting out not for any

duding a new element into criminal law. Laws are made for the government of actions, and while they cannot interfere with mere religious belief and opinions, they may with practices.

Id. at 819.

491. See *Cude*, 377 S.W.2d at 819.

492. See *id.* See also *Mosier v. Barren County Bd. of Health*, 215 S.W.2d 967, 968–69 (Ky. 1948) (upholding compulsory vaccination of school child); *Bd. of Ed. of Mountain Lakes v. Maas*, 152 A.2d 394, 405–07 (N.J. 1959); *Sadlock v. Bd. of Ed.*, 37 N.J.L. 85, 90–91, 58 A.2d 218, 221–22 (N.J. 1948); *In re Whitmore*, Dom. Rel. Ct. N.Y., 47 N.Y.S.2d 143, 145–46 (N.Y. 1944); *City of New Braunfels v. Waldschmidt*, 109 Tex. 302, 305–06, 207 S.W. 303, 308–09 (Tex. 1918). See also *State v. Perricone*, 181 A.2d 751, 759–60 (N.J. 1962) (requiring blood transfusion for infant against parent’s religious beliefs); *In re Clark*, Ohio Com. Pl., 185 N.E.2d 128, 132 (Ohio 1962). Despite the weight of the aforementioned authority, religious objections to vaccinations were responsible for numerous measles cases during the American epidemic of 1989 to 1991. See, e.g., *Measles Outbreak in Philadelphia Religious Schools Leaves 5 Dead*, CHI. TRIB., Feb. 17, 1991, at C6.

493. See *Hinman et al.*, *supra* note 376, at 124.

deeply held belief, but because it was easier to do so than to fulfill the requirements of childhood immunization laws.⁴⁹⁴ By far the vast majority of exemptions in states that allow both religious and philosophical opt-outs are of the latter variety. In Washington, up to 95% of all exemptions were claimed for personal, not religious, reasons.⁴⁹⁵ Data from Colorado show a similar pattern, as parents who opted out of vaccination were 10 times more likely to choose philosophical reasons than religious ones.⁴⁹⁶ Studies confirm that many California exemptors did so because it was more trouble to go through the effort of finding immunization records.⁴⁹⁷

Worse, allowing philosophical exemptions permits financial incentives to distort sound public policy decisionmaking.⁴⁹⁸ Where schools cannot receive full government funding for teachers and books until they show that all children are immunized *or* legally opted out, the temptation for administrators to encourage non-compliant parents to check the box opting out may be too much for cash-strapped educators to resist.

While states are understandably concerned about trampling too heavily on individual rights and freedoms, they should enact guidelines to prevent philosophical exemptions of convenience from threatening overall public health safety.

3. *Medical Exemptions Should be Allowed Where Legitimately Necessary*—Medical exemptions in the case of children who are immuno-compromised (due to HIV or cancer) or otherwise severely allergic to vaccines should be permitted. No regulation should require vaccination where the harm imposed is greater than the benefit received. Quite sensibly then, all fifty states allow such exemptions today.⁴⁹⁹

It is important to note, however, that medical exemptions to compulsory immunization laws are appropriate only in exceptional cases. A physician must verify the medical necessity of the exemption, and his or her decision to do so must be based on scientifically recognized criteria. New York is one of the only states in the country to enforce such a stance, denying bogus requests

494. See *id.* at 125 (describing California's experience with exemptions to compulsory immunization laws).

495. See Jancin, *supra* note 28.

496. See Edwards, *supra* note 36 (describing Feiken's Colorado study, which found that 1.87% of children are exempted for philosophical reasons, 0.12% for medical purposes, and 0.19% for religious objections).

497. See Hinman et al., *supra* note 376, at 125.

498. See Marcuse, *supra* note 29.

499. See Hinman et al., *supra* note 376, at 124.

where they are “based on quackery.”⁵⁰⁰ Most other states have never denied a single claim for any variety of exemption.⁵⁰¹

B. Make the Exemption Process a Thoughtful One

States should at the very least ensure that their exemption processes are better designed to encourage deliberative thought and better enforced to verify sincerity of beliefs. Today, parents can simply check a box in many states to opt out of vaccination, no questions asked.⁵⁰² The vast majority of states do not enforce any limitations on exemptions, as 32 of 48 states which allow religious and/or philosophical exemptions have never denied a single claim.⁵⁰³ When exemptions are this easy to receive, it is far too likely that they will substitute for simply forgetting to go to the doctor, or even choosing not to immunize because doing so is “more trouble than it is worth.” Some parents might also wish to avoid the cost of seeing a physician, though financially strapped parents can avail themselves of free vaccination under the Comprehensive Childhood Immunization Act of 1993 and the Vaccines for Children program.⁵⁰⁴ The law should never make it easier to opt out of receiving vaccines than it is to get them.

Predictably, the complexity of each state’s exemption process affects the percentage of students who choose to legally opt out of vaccination.⁵⁰⁵ A study by J.S. Rota et al. found that of the 19 states with the highest level of complexity required to receive an exemption, *none* had more than 1% of students exempted from

500. See McNeil, *Worship Optional*, *supra* note 4, at D4. See also *Lynch v. Clarkstown Cent. Sch. Dist.*, 590 N.Y.S.2d 687, 690 (N.Y. Sup. Ct. 1992) (holding that school district was not required to accept at face value a note from child’s physician stating that immunizations were contraindicated; its denial of medical exemption was rationally based and was not arbitrary or capricious).

501. Thirty-two of forty-eight states that allow religious or philosophical exemptions have never denied one. See Hinman et al., *supra* note 376, at 125.

502. For a sample “check the box only” form, see *infra*, Exhibit A.

503. See *id.*

504. See Hodge & Gostin, *supra* note 26, at 881–82. Furthermore, a panel of medical experts recently recommended that the government should require all insurance plans to cover vaccinations, and offer vouchers so that people without insurance can get their shots. See Robert Pear, *Panel Urges U.S. to Broaden Role in Vaccinations*, N.Y. TIMES, Aug. 5, 2003, at A1.

505. See J.S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645 (2001).

compulsory vaccination laws.⁵⁰⁶ By contrast, five of the fifteen states with the simplest exemption process witnessed opt-out rates of greater than 1%.⁵⁰⁷ The degree of "red tape" involved thus significantly affects exemption rates, especially exemptions of convenience. In states like Washington, which require the mere checking of a box to claim a legally valid exemption, up to 95% of all exemptions filed are due to "personal reasons" rather than due to sincere religious objections.⁵⁰⁸

More crucially but not surprisingly, studies have shown that a direct link exists between children who are exempted from mandatory immunizations and children who are at risk of contracting serious life-threatening diseases.⁵⁰⁹ Daniel Salmon found that children of parents who filed religious or philosophical exemptions had a 35 times greater risk of contracting measles than did children who were vaccinated against measles.⁵¹⁰ A Colorado report confirmed that students with personal exemptions were 22 times more likely to acquire measles and 6 times more likely to acquire pertussis (whooping cough) than their immunized peers.⁵¹¹ Jancin reports that immunization-exempted children are also more likely to spread diseases to others, and that schools with higher levels of exemptions are more likely to experience outbreaks of vaccine-preventable diseases than their better-vaccinated counterparts.⁵¹²

Given this data, states should enact reasonable exemption processes that prevent opt-outs of convenience while respecting sincerely held individual rights and beliefs. In New York City procedures have been set up to ensure that any exemption request is carefully reviewed. While the state allows religious exemptions, the Board of Education requires applicants to write a detailed letter

506. See *id.* In 2002, the best state overall with respect to vaccination coverage was Massachusetts, as 86% of toddlers received *all* mandatory inoculations on time. See Neergaard, *supra* note 423, at A2.

507. See Rota et al., *supra* note 505. According to the CDC, Colorado has the most immunization laggards, as only 62.7% of toddlers receive all of their mandatory immunizations on time. Washington, Arizona, Idaho, Kansas, Louisiana, Montana, New Mexico, Oklahoma and Texas round out the bottom 10 states in terms of vaccination rates. See Neergaard, *supra* note 423, at A2.

508. See Jancin, *supra* note 28.

509. See *id.*

510. See D.A. Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws*, 282 J. AM. MED. ASS'N 47 (1999). Salmon's study covered the period between 1985 through 1992. *Id.*

511. See Feiken et al., *supra* note 402. See also Edwards, *supra* note 36 (discussing the consequences of the high exemption rate in Colorado, and noting that 1.87% of children are exempted for philosophical reasons, 0.12% for medical purposes, and 0.19% for religious objections); Jancin, *supra* note 28.

512. See Jancin, *supra* note 28.

discussing their religious beliefs and reason for wanting to opt-out of immunization. The Board further takes the stance that no established religion formally forbids vaccination.⁵¹³ Principals are fined \$2,000 per day for any unvaccinated child in school, and the City rejects “bogus” medical exemption requests if they are “based on quackery.”⁵¹⁴

Dr. Edgar Marcuse of the University of Washington similarly recommends that states enact “thoughtful exemption process[es] with no onerous hurdles” to balance individual liberties with public safety.⁵¹⁵ He laments the fact that schools currently have financial incentives to encourage parents to opt out in order to receive government funding. Sound government policy should not tie funding to children’s immunization status, because cash-strapped educators may not be able to resist the temptation to encourage parents to opt-out of vaccination if they have not already completed their child’s required immunization schedule.⁵¹⁶ State and federal laws must reverse these perverse financial incentives immediately. Schools should be awarded funds for children who are temporarily excluded because their immunization status is incomplete.⁵¹⁷

Thoughtful exemption processes might also include health department seminars for parents on the benefits and risks of vaccination so that their decision will be an informed one. Those seeking religious exemptions should be asked to describe their sincere religious objection to vaccinations. A letter from a church official confirming the deeply held objection might also be required. Likewise, medical exemptions must be carefully documented, and backed up by science. In addition, states should be allowed to verify the sincerity and validity of the claims made by parents (contrary to holdings of some courts).⁵¹⁸ Requirements to claim an exemption lose all meaning if they are never enforced to begin with.⁵¹⁹ It is the duty of legislatures and health departments

513. See McNeil, *Worship Optional*, *supra* note 4, at D4.

514. See *id.*

515. See Marcuse, *supra* note 29. While Marcuse is concerned about reducing convenience exemptions, he is understandably wary of imposing formidable barriers to exemptions for those with deeply held religious or personal beliefs.

516. See Jancin, *supra* note 28.

517. See Marcuse, *supra* note 29.

518. See, e.g., *In re LePage*, 18 P.3d 1177, 1180 (Wyo. 2001) (holding that the Department of Health cannot inquire into sincerity of mother’s religious beliefs in seeking exemption from vaccination laws).

519. See Hinman et al., *supra* note 376, at 125 (pointing out that 32 of 48 states with religious or philosophic exemptions have never denied a single claim for one).

to enact sensible criteria for those seeking to qualify for religious or medical exemptions, and to have administrators enforce them as intended.

C. Public Relations Campaign

One final concern as legislatures push to limit the proliferation of religious and philosophical exemptions to vaccination is that laws that punish antivaccinationists too severely may cause a public relations backlash that inhibits their success. For instance, in Leicester, England, an 1867 act penalized monetarily and criminally those parents who failed to ensure that their children were properly vaccinated.⁵²⁰ Rather than result in increased compliance with mandatory immunization laws, opposition to vaccination grew—based on medical concerns and more importantly, the preservation of personal liberties. As a consequence, the vaccination rate went from over 90% in 1872 to a mere 3% in 1892.⁵²¹ Over 3,000 fines and 60 prison sentences were imposed on parents for not vaccinating their children,⁵²² but the intended goal of increased immunization coverage was never achieved.

A public relations campaign must therefore accompany any effort to enact thoughtful exemption processes in order to educate parents regarding the risks of diseases versus the risk of vaccines. Given the amount of conflicting information spread by the media and internet today, the state must disseminate accurate data to the public in order to ensure that parents affirmatively *desire* to immunize their children instead of doing it reluctantly or under penalty of fines or imprisonment. This is not just a legal or medical problem; the success of vaccination programs depends on upon achieving broad public support. Because of the need for widespread public consensus, using absolute mandates to increase immunization levels is probably not a wise social policy, and could produce a serious backlash. Rather, educational programs for parents concerning vaccination benefits and risks may do far more to alleviate fears and encourage immunization. The average parent thus needs to know and understand the actual risks presented in order to create societal “buy in” to immunization programs.

520. See Hodge & Gostin, *supra* note 26, at 848.

521. See *id.*

522. See *id.* (citing HERVE BAZIN, THE ERADICATION OF SMALLPOX: EDWARD JENNER AND THE FIRST AND ONLY ERADICATION OF A HUMAN INFECTIOUS DISEASE 130 (2000)).

Layman's language should be used—on TV, in magazines, newspapers, etc.—and not just in the pediatrician's office. As Peter Davies points out, the best way to reduce misconceptions and mistrust is to address the roots of anti-government, new-age beliefs rather than to speak as one would to a group of healthcare practitioners.⁵²³ Government cannot preach to the choir; it must speak to the skeptical parent on the verge of making the vaccination decision.

Thus, legislatures will be charged with reaching political compromises that protect the public's health while respecting individual rights.⁵²⁴ While it is important to recognize parents' civil liberty interests to make choices regarding their children's health, it is also true that certain individual rights yield to society's best interests. To soften concerns regarding limitations on personal freedoms, it should be made clear that all parents will be entitled to free vaccinations for their children,⁵²⁵ and that any injuries that result will be fully compensated.⁵²⁶ Congress has already provided for both of these contingencies, though little public awareness of that fact exists.

CONCLUSION

Few dispute that vaccinations are one of the greatest public health achievements of all time, perhaps ranking second only to the advent of clean water. It is their monumental success which ironically threatens their future. As horrific diseases like smallpox and polio have been eradicated or dramatically curtailed, the current generation no longer fears them like our grandparents did. Today, one is more likely to hear about vaccine safety risks than she is about vaccine benefits. The media and internet highly publicize stories regarding links between immunizations and autism, leading

523. See Davies, *supra* note 291.

524. See Hinman et al., *supra* note 376, at 126–27.

525. The Institute of Medicine has recently recommended that the government require insurance companies to cover vaccinations and that the government provide vouchers to Americans who do not have insurance so that access to immunizations is never hampered by their cost. See Pear, *supra* note 504.

526. The National Childhood Vaccine Injury Act provides compensation to any child who suffers an injury at the hands of mandatory immunizations, and the Comprehensive Childhood Immunization Act of 1993 provides an entitlement to free vaccines for eligible children through the Vaccines for Children program. See Jeanne M. Santoli et al., *Vaccines for Children Program, United States, 1997*, 104 PEDIATRICS 1 (1999).

well-meaning parents to question whether the cure is worse than the disease.

State legislatures and health departments must strike a balance between the legitimate concerns of parents regarding immunizations and overall public health safety. If vaccination coverage falls too low, outbreaks of measles, polio, whooping cough and a number of other diseases will not be far behind. While individual freedoms and rights must be respected, parents and schools must not use vaccination exemptions as opt-outs of convenience. State health officials should ensure that it is not easier to check a box to avoid vaccination than it is to complete the required childhood immunization schedule. Financial incentives currently provided by the government compound the problem, as schools may be tempted to encourage children with incomplete immunization records to claim exemptions so that the underfunded institutions can receive full monetary support for the child.

In the final analysis, sound public policy dictates that laws must be modified to create thoughtful exemption processes. States have a *parens patriae* duty to exercise their police power in the best interests of the public and to protect the weak. While individualism and civil liberties are respected in America, this nation must also preserve the health of innocent children and society as a whole. Religious and philosophical exemptions must be carefully scrutinized to ensure that they do not proliferate unchecked. Society must educate parents regarding the true risks and benefits of immunizations versus the diseases they protect against in order to provide accurate information to decisionmakers. It should not take another tragedy before states stem the tide of vanishing vaccinations in America.

EXHIBIT A: STATEMENT OF EXEMPTION TO IMMUNIZATION LAW

NOTICE:

Your child can be exempted (excused) from immunization for medical, personal or religious reasons. However, if there is an outbreak of a vaccine-preventable disease that your child has not been immunized against, she or he can be excluded from school, preschool or child care until the outbreak is over.

MEDICAL EXEMPTION

I certify that the child named on this form is medically exempted from the requirement for the following vaccines:

Vaccine(s) _____ Until _____ Date _____

Type or Print Physician's name _____ Date _____

Physician's Signature _____

PERSONAL EXEMPTION

RELIGIOUS EXEMPTION

I am opposed to immunization. I understand that my child can be excluded from attendance during an outbreak.

I do not wish my child to receive the following vaccine(s):

Vaccine(s) _____ Date _____

Signature of Parent or Guardian Date _____