

JACOBSON REVISITED: MANDATORY POLIO VACCINATION AS AN UNCONSTITUTIONAL CONDITION

INTRODUCTION

When the Centers for Disease Control and Prevention (“CDC”) published their “Ten Great Public Health Achievements” for the United States from 1900 to 1999, vaccination was the first achievement listed.¹ The widespread use of vaccines has eradicated smallpox globally, and has eliminated wild-type polio from the Western Hemisphere since 1991.² As a result, smallpox vaccination has since been discontinued.³ According to the World Health Organization (“WHO”), polio transmission will likely be interrupted by the end of 2004, and eradication would be certified at least three years later.⁴ A key program in assuring full vaccine coverage is mandatory immunization for admission to public schools.

Although vaccines are a tremendously powerful tool in fighting the spread of infectious diseases, they do rarely cause adverse events, including anaphylaxis, residual encephalopathy, paralysis, and death.⁵ Facing large tort claims arising from these adverse events, vaccine manufacturers expressed concerns that they could no longer afford to continue making these products. Fearing a vaccine shortage, Congress passed the National Vaccine Injury Compensation Act,⁶ which created the National Vaccine Injury Program (“NVICP”)⁷ and caps damages for pain and suffering at \$250,000.⁸

Parents in the United States face a difficult choice: either immunize their children for polio, a disease which no longer exists in the Western Hemisphere, and expose their children to potentially dangerous side effects,

¹ Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 12, 241(1999) [hereinafter CDC, *Ten Great Achievements*].

² Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children—United States, 1900-1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 12, 243, 244 (1999) [hereinafter CDC, *Achievements in Public Health*].

³ *Id.*

⁴ David L. Heymann, *Polio Eradication: Finishing the Job and Protecting the Investment*, 82 BULL. OF THE WORLD HEALTH ORG. 1, 1 (2004).

⁵ Robert T. Chen, *Safety of Vaccines*, in VACCINES 1144, 1157-59 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

⁶ 42 U.S.C.A. §§ 300aa-1—300aa-34 (2003).

⁷ 42 U.S.C.A. § 300aa-10 (2003).

⁸ 42 U.S.C.A. § 300aa-15(a)(4) (2003).

or opt out of sending their children to public schools. Furthermore, if their children are injured by a polio vaccination, NVICP limits their remedy. *Jacobson v. Massachusetts*⁹ is the archetypical case illustrating that states have the public health police power to require vaccination for their citizens. However, *Jacobson* was decided in 1905 when smallpox was still a global threat. If a state were to require smallpox vaccination today, the Supreme Court would have a more difficult decision to make.

This Comment posits that mandatory polio vaccination, by analogy to mandatory smallpox vaccination, is an unconstitutional condition when used as a requirement for admission to public schools. The history of vaccines, the polio vaccine, school vaccination programs, and NVICP are discussed in Part I. Part II examines *Jacobson v. Massachusetts* and the scope of a state's public health police powers. *Jacobson v. Massachusetts* is re-examined as a modern case in Part III. Part IV describes the doctrine of unconstitutional conditions, and applies the doctrine to mandatory vaccinations. Part V applies the modernized holding in *Jacobson* to the polio vaccine, and provides recommendations for further use of the polio vaccine.

I. BACKGROUND

Vaccines have been used to prevent the spread of disease for over 200 years, starting with the smallpox vaccine.¹⁰ Vaccines have eradicated smallpox,¹¹ and widespread vaccination has brought polio to the cusp of eradication.¹² In the United States, mandatory vaccination programs for public school students help to assure nearly universal coverage.¹³ Although generally safe, vaccines occasionally cause adverse events. In an effort to protect vaccine manufacturers from lawsuits, thus assuring a continued source of vaccines, Congress created a compensation program for children injured by vaccinations.¹⁴ This Part examines the evolution of vaccine technology and the law.

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

¹⁰ Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, in *VACCINES* 74, 75 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

¹¹ World Health Org., *Smallpox Fact Sheet*, at <http://www.who.int/mediacentre/factsheets/smallpox/en/>, (last visited Aug. 20, 2005).

¹² See Heymann, *supra* note 4, at 1.

¹³ James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 868-73 (2001/2002).

¹⁴ 42 U.S.C.A. §§ 300aa-1—300aa-34 (2003).

A. *History of Vaccines*

The smallpox vaccine, developed in 1796 by Edward Jenner,¹⁵ was the first scientific attempt to prevent the spread of disease through inoculation.¹⁶ Building upon folklore that those who contracted cowpox (a disease caused by the vaccinia virus) did not develop smallpox,¹⁷ Jenner demonstrated that people inoculated with material from a human pustular cowpox lesion were protected from smallpox infection.¹⁸ By 1864, inoculation material was harvested from pustules on cows, as this provided a larger and safer supply of material.¹⁹ Although the use of cowpox to prevent contracting smallpox was a significant discovery, widespread use of this technique was limited because the inoculation material was viable for only one or two days after harvest.²⁰

By the late 1940's, advances in vaccine manufacturing led to the development of highly stable vaccine formulations, particularly through the use of freeze-drying.²¹ The freeze-dried formulation allowed the vaccine to be preserved indefinitely when refrigerated, and to be effective even after six to nine months of exposure to high summer temperatures.²² International health agencies realized that this more stable formulation could be used to reach remote and less technologically advanced parts of the world, and a global eradication program was enacted in 1959.²³ The last naturally occurring case of smallpox was recorded on October 26, 1977 in Merka, Somalia,²⁴ and worldwide eradication was certified by WHO in 1980.²⁵

The development of other vaccines has caused a tremendous decrease in morbidity and mortality associated with other diseases, particularly from diphtheria, pertussis, tetanus, paralytic poliomyelitis, measles, mumps, rubella, and *Haemophilus influenzae* type b.²⁶ Unlike the smallpox vaccine, which uses a live virus to invoke immunity, newer vaccines use inactivated or attenuated viruses or bacteria, toxoid proteins, peptides, polysaccharides, protein-polysaccharide conjugates, polyclonal or monoclonal antibodies,

¹⁵ See Henderson & Moss, *supra* note 10, at 75.

¹⁶ Susan L. Plotkin & Stanley A. Plotkin, *A Short History of Vaccination*, in VACCINES 1, 2 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

¹⁷ *Id.*

¹⁸ Henderson & Moss, *supra* note 10, at 75.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.* at 81.

²³ *Id.* at 75.

²⁴ Henderson & Moss, *supra* note 10, at 76.

²⁵ The World Health Org., *supra* note 11.

²⁶ CDC, *Achievements in Public Health*, *supra* note 2, at 245.

and DNA.²⁷ With the exception of safe water, no advancement in public health has had a larger effect on mortality reduction and population growth, including antibiotics.²⁸ In 1999, CDC released a list of the “Ten Great Public Health Achievements” in the United States from 1900 to 1999; vaccination was the first achievement on that list.²⁹

B. *Polio and the Polio Vaccine*

Poliomyelitis is a highly contagious infectious disease caused by poliovirus.³⁰ Infection with poliovirus can cause aseptic meningitis or paralytic disease.³¹ Polio can lead to disfigurement and paralysis, including paralysis of the respiratory muscles.³² After thirty to forty years, 25% to 40% of those who contracted paralytic polio during childhood can experience muscle pain and weakness, or develop new paralysis.³³ Paralytic polio is fatal in 2% to 10% of cases.³⁴

Poliomyelitis is transmitted by person-to-person via fecal-oral and oral-oral routes, or less frequently by a common vehicle such as water or milk.³⁵ therefore, poliovirus transmission can be prevented by inhibiting replication at and dissemination from the gastrointestinal tract.³⁶ Humans are the only reservoir for poliovirus, therefore, the disease can be eradicated by eliminating the virus from the human population.³⁷ Before the polio vaccine was discovered, poliomyelitis was the leading cause of permanent disability.³⁸

By January 2004, worldwide use of the polio vaccine eliminated polio in all but six countries (Afghanistan, Egypt, India, Niger, Nigeria, and Pakistan), and WHO predicted that transmission of the disease would be inter-

²⁷ Ronald W. Ellis, *New Technologies for Making Vaccines*, in VACCINES 881, 882-83 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

²⁸ Plotkin & Plotkin, *supra* note 16, at 1.

²⁹ CDC, *Ten Great Achievements*, *supra* note 1, at 241.

³⁰ Ctrs. For Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Poliomyelitis Prevention in the United States*, MORBIDITY & MORTALITY WKLY. REP. RECOMMENDATIONS & REPS., May 19, 2000, at 3 [hereinafter CDC, *Poliomyelitis Prevention*].

³¹ *Id.*

³² Frederick C. Robbins, *The History of Polio Vaccine Development*, in VACCINES 13 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

³³ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 3.

³⁴ *Id.*

³⁵ Roland W. Sutter et al., *Live Attenuated Polio Vaccines*, in VACCINES 371, (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999) [hereinafter Sutter et al., *Live Attenuated Polio Vaccines*].

³⁶ *Id.* at 367.

³⁷ See CDC, *Poliomyelitis Prevention*, *supra* note 30, at 4.

³⁸ Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 365.

rupted by the end of 2004.³⁹ However, a large polio outbreak occurred in the Nigerian state of Kano, where local leaders have held up vaccination activities because of their distrust of the vaccine and of Western public health practitioners.⁴⁰ As of September 1, 2004, Nigeria's 491 confirmed polio cases represent 78% of all the world's cases, and has caused a spread to at least 10 African countries that were previously polio free.⁴¹ Despite this setback, WHO still maintains that global polio eradication can be achieved in 2005 or 2006.⁴² According to WHO's Chris Maher, "Nigeria is not a huge technical challenge . . . If we have three, four, five good rounds [of immunization], that's it. The game is over."⁴³ Nigeria is more sparsely populated than other countries that have experienced polio reintroduction in the past, such as Lagos, and WHO intervention has re-eradicated polio in such situations.⁴⁴ Therefore, WHO is confident that the recent surge in and spread out of Nigeria can be controlled quickly.⁴⁵

Once transmission is interrupted, eradication of polio will be certified in at least three years.⁴⁶ Vaccinations must continue in these countries until certification to prevent outbreaks caused by vaccine-related polioviruses.⁴⁷ There are two types of polio vaccine: inactivated polio vaccine ("IPV") and live attenuated polio vaccine, which is also called oral polio vaccine ("OPV"). The advantages and drawbacks of these two vaccines are discussed below.

1. Oral Polio Vaccine

As its name implies, OPV is administered orally using a dropper,⁴⁸ and results in both humoral (systemic) and mucosal (local) immunity.⁴⁹ Mucosal immunity prevents poliovirus replication and excretion in the pharynx and

³⁹ Heymann, *supra* note 4, at 1. For example, 225 confirmed wild poliovirus cases were reported in India in 2003, down from 1,600 such cases in 2002 in that country. Ctrs. For Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Progress Toward Poliomyelitis Eradication—India, 2003*, 53 MORBIDITY & MORTALITY WKLY. REP. 238, 239, 241 (2004).

⁴⁰ Leslie Roberts, *Polio: The Final Assault?*, 303 SCI. 1960, 1967 (2004).

⁴¹ John F. Modlin, *Poliomyelitis in the United States*, 292 JAMA 1749, 1750 (2004).

⁴² Craig Timberg, *In Nigeria, Talking Up Two Drops of Vaccine*, WASH. POST, Nov. 25, 2004, at A18. ("With the rate of vaccinations rising so swiftly, global health officials are now predicting that polio will be eradicated by 2005 or 2006.")

⁴³ Roberts, *supra* note 40, at 1968.

⁴⁴ *See id.*

⁴⁵ *Id.*

⁴⁶ Heymann, *supra* note 4, at 1.

⁴⁷ *See infra* Part I.B.1.

⁴⁸ Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 379.

⁴⁹ *Id.* at 381.

intestine.⁵⁰ Because poliovirus is transmitted by the fecal-oral route, the ability of OPV to prevent excretion from the intestine has a major advantage over IPV⁵¹ in reducing the circulation of poliovirus, particularly in developing countries with poor hygiene.⁵² For this reason, OPV is also the only vaccine recommended to control outbreaks of polio, and the United States maintains an emergency stockpile of OPV.⁵³ The active component of OPV is a live attenuated form of the poliovirus, which has a high degree of infectivity in the human intestinal tract and causes the production of a neutralizing antibody, but does not cause paralytic disease in humans.⁵⁴ In other words, the live attenuated virus is sufficiently infectious to invoke an immune response, but does not actually cause polio.

The major adverse event associated with OPV is vaccine-associated paralytic poliomyelitis (“VAPP”), where patients develop poliomyelitis after receiving the vaccine.⁵⁵ VAPP has also been associated with people who came in contact with OPV recipients.⁵⁶ To reduce the risk of VAPP, and considering that the near global eradication of polio has substantially reduced the likelihood of poliovirus importation into the United States, the Advisory Committee on Immunization Practices (“ACIP”) recommended on June 17, 1999 that use of OPV be discontinued, and that IPV should be used for routine childhood polio vaccination.⁵⁷

2. Inactivated Polio Vaccine

IPV is a mixture of three polioviruses that are inactivated by exposure to formalin.⁵⁸ After inactivation, the viruses are tested for residual infectivity to assure that the virus is fully inactivated and will not cause polio.⁵⁹ IPV is injected either subcutaneously or intramuscularly.⁶⁰ IPV produces neutralizing antibodies in the gastrointestinal tract, but to a lesser degree than OPV.⁶¹ Therefore, IPV recipients can excrete poliovirus after viral

⁵⁰ *Id.*

⁵¹ *See infra* Part I.B.2.

⁵² Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 383.

⁵³ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 14.

⁵⁴ *See* Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 377.

⁵⁵ *Id.* at 386.

⁵⁶ *See* Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 377.

⁵⁷ *Id.* at 18-19.

⁵⁸ Stanley A. Plotkin et al., *Inactivated Polio Vaccine*, in *VACCINES* 345, 346 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999).

⁵⁹ *Id.* at 347.

⁶⁰ *Id.* at 348.

⁶¹ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 15.

challenge, even though they do not become infected.⁶² For this reason, OPV can protect more people who are susceptible in a population, making it the preferred vaccine over IPV during an outbreak.⁶³

Although IPV is safe⁶⁴ and efficacious,⁶⁵ a manufacturing accident by Cutter Laboratories in 1955 created two lots of IPV that were not fully inactivated.⁶⁶ About 70,000 children received these lots, and 10% to 25% of the children became infected,⁶⁷ resulting in approximately one case of paralytic polio in every 100 to 600 infections.⁶⁸ Since this incident, increased safety precautions were instituted and there have been no other cases of defective manufacture of IPV.⁶⁹ IPV contains trace amounts of streptomycin, polymixin B, and neomycin, and can, therefore, cause severe allergic anaphylactic reactions in patients who are allergic to these antibiotics.⁷⁰ Although no serious adverse events have been associated with IPV,⁷¹ aside from the Cutter incident, any vaccine, including IPV, can cause a serious adverse reaction.⁷²

C. *Mandatory Vaccination Programs*

In an effort to maximize vaccination rates, states began implementing mandatory vaccination policies for children attending public schools.⁷³ In 1827, Boston was the first city to require vaccination for public school students.⁷⁴ The policy was later enacted throughout Massachusetts, and was adopted by other states in the Northeast, Midwest, South, and West.⁷⁵ Today, all fifty states require proof of immunization for their public school students.⁷⁶ In most states, children can be exempted from immunization if their parents can show that vaccinations are against their religious beliefs,

⁶² Plotkin et al., *supra* note 58, at 354.

⁶³ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 15.

⁶⁴ Plotkin et al., *supra* note 58, at 356.

⁶⁵ *Id.* at 354.

⁶⁶ *Id.* at 356.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 356-357.

⁷⁰ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 14.

⁷¹ *Id.*

⁷² U.S. Dep't of Health & Human Servs., Ctrs. For Disease Control & Prevention, Nat'l Immunization Program, *Vaccine Information Statement - Polio*, available at <http://www.cdc.gov/nip/publications/VIS/vis-IPV.pdf> (last visited Oct. 14, 2005).

⁷³ Hodge, Jr. & Gostin, *supra* note 13, at 851.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 868-73.

and some states provide philosophic exemptions, which are not based on spiritual or religious grounds.⁷⁷

D. *National Vaccine Injury Compensation Program*

Adverse events associated with vaccinations are rare, but still occur because no vaccine is perfectly safe or effective.⁷⁸ As successful tort claims increased, vaccine manufactures became concerned that making vaccines would no longer be a profitable endeavor, and considered withdrawing from the market. To assure a supply of vaccines while still providing a financial remedy to those injured, Congress passed the National Childhood Vaccine Injury Act of 1986 (“the Act”).⁷⁹ The Act established the National Vaccine Injury Compensation Program,⁸⁰ which provides a no-fault compensation plan, with damages for pain and suffering capped at \$250,000.⁸¹ If the recipient of a covered vaccine dies from complications related to the vaccination, the recipient’s estate receives an award of \$250,000.⁸²

Eligibility for recovery is based on the Vaccine Injury Table (“the Table”),⁸³ which lists vaccines and specific adverse events. The Table also provides a time period in which the adverse events must manifest to establish eligibility. For example, if a non-immunodeficient recipient of OPV develops paralytic polio within thirty days of vaccination, the recipient qualifies for NVICP.⁸⁴ The Table includes vaccines against diphtheria, tetanus, pertussis, measles, mumps, rubella, polio (both OPV and IPV), *Haemophilus influenzae* type b, hepatitis B, varicella, rotavirus gastroenteritis,

⁷⁷ *Id.*

⁷⁸ Chen, *supra* note 5, at 1144.

⁷⁹ 42 U.S.C. §§ 300aa-1 to -34 (2004). *See also* Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994) (“[A]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufactures in the market.”); Charette v. Sec’y of Dept. of Health & Human Servs., 33 Fed. Cl. 488, 492 (1995) (“The National Vaccine Injury Compensation Program was created to ensure the availability of childhood vaccines and provide fair and simple compensation to those who are injured by such vaccines.”); Steve P. Calandrillo, *Vanishing Vaccinations: Why are so Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 408 (2004).

⁸⁰ 42 U.S.C. § 300aa-10 (2004).

⁸¹ 42 U.S.C. § 300aa-15(a)(4) (2004). *See also* Calandrillo, *supra* note 79, at 410.

⁸² 42 U.S.C. § 300aa-15(a)(2) (2004).

⁸³ 42 U.S.C. § 300aa-14 (2004).

⁸⁴ 42 U.S.C. § 300aa-14(a) (2004).

and *Streptococcus pneumoniae*.⁸⁵ Any vaccines not included in the Table, such as smallpox, do not qualify for NVICP.

These awards are all paid from the Vaccine Injury Compensation Trust Fund (“the Fund”),⁸⁶ a statutorily created fund generated by a seventy-five cent tax on each dose of specific vaccines.⁸⁷ These “taxable vaccines” are those against diphtheria, tetanus, pertussis, measles, mumps, rubella, polio (both OPV and IPV), *Haemophilus influenzae* type b, hepatitis B, chicken pox, rotavirus gastroenteritis, and *Streptococcus pneumoniae*.⁸⁸ Vaccines containing a combination of these antigens are taxed seventy-five cents per component.⁸⁹ Therefore, everyone who receives these taxable vaccines pays into the Fund via the tax, and the Fund is used to compensate those who are injured by the vaccines listed in the Table.⁹⁰

The tax thus spreads the burden of adverse events throughout the population of vaccine recipients, rather than imposing the burden on vaccine manufacturers.⁹¹ Those who choose to be vaccinated provide the compensation for the adverse events suffered by other vaccinated individuals. This shields manufacturers from liability, which reduces the market price of vaccines; if manufacturers had to use their own resources to compensate every injured vaccine recipient, then this compensation would be factored into the price of each individual dose of vaccine sold.⁹² This would have a result similar to the seventy-five cent tax imposed by the government, but with potentially worse consequences. First, without a limit on damages, injured vaccine recipients could receive multi-million dollar verdicts.⁹³ Distributing these costs across each dose of vaccine would require more than a seventy-five cent price increase, which would result in higher vaccine prices than are currently observed. This would lead to a decrease in demand for vaccine, as it could become too expensive for insurance companies, public health agencies, and private individuals to obtain vaccine coverage

⁸⁵ See 42 U.S.C. § 300aa-14(a) (2004); U.S. Dep’t of Health & Human Servs., Health Res. & Servs. Admin., *National Childhood Vaccine Injury Act Vaccine Injury Table*, available at <http://www.hrsa.gov/osp/vicp/table.htm> (last visited Nov. 14, 2004).

⁸⁶ 26 U.S.C. § 9510 (2004).

⁸⁷ 26 U.S.C. § 4131(b)(1) (2004).

⁸⁸ 26 U.S.C. § 4132(a)(1) (West 2004), amended by American Jobs Creation Act of 2004, Pub. L. No. 108-357, § 889-90, 118 Stat. 1418, 1643-44 (2004) (adding vaccines against hepatitis A and trivalent vaccines against influenza to the list of “taxable vaccines”).

⁸⁹ 26 U.S.C.A. § 4131(b)(2) (West 2004). For example, the measles, mumps, rubella vaccine (“MMR”) contains three different components, one for each disease. Therefore MMR vaccines are taxed \$2.25 per dose: (three components) X (\$0.75 per component) = \$2.25.

⁹⁰ See Mary Beth Neraas, *The National Childhood Vaccine Injury Act Of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 163 (1988).

⁹¹ *Id.*

⁹² See *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994).

⁹³ See Neraas, *supra* note 90, at 164.

at current levels.⁹⁴ Second, large damages awards could drive manufacturers out of the market entirely, which would limit the amount of vaccine available, thus reducing the number of vaccinated individuals in the population.⁹⁵

II. *JACOBSON V. MASSACHUSETTS*—STATE POLICE POWERS ENCOMPASS MANDATORY VACCINATION PROGRAMS

Citizens have challenged mandatory vaccination laws on many occasions.⁹⁶ Perhaps the most important such case is *Jacobson v. Massachusetts*,⁹⁷ which held that mandatory vaccinations fall within the police powers of the states.

A. *Background and Holding of Jacobson v. Massachusetts*

In 1902, a Massachusetts statute gave local boards of public health the power to require vaccination for the residents of their respective towns or cities.⁹⁸ In response, on February 27, 1902 the Board of Health of Cambridge required all residents of the city to be vaccinated for smallpox.⁹⁹ Henning Jacobson refused to be vaccinated, claiming that the statute abridged his privileges as a citizen, and deprived him of liberty without due process of law, thus violating his Fourteenth Amendment rights.¹⁰⁰ The Su-

⁹⁴ See *Schafer*, 20 F.3d at 4.

⁹⁵ *Id.*

⁹⁶ See, e.g., *Zucht v. King*, 260 U.S. 174 (1922) (upholding mandatory vaccination for public and private school students); *Viemeister v. White*, 72 N.E. 97 (N.Y. 1904) (upholding mandatory smallpox vaccination for students); *Ritterband v. Axelrod*, 562 N.Y.S.2d 605 (Sup. Ct. 1990) (upholding mandatory rubella vaccinations for physicians); *Duffield v. Sch. Dist. of Williamsport*, 29 A. 742 (Pa. 1894) (upholding mandatory smallpox vaccination for students); *State ex rel. Cox v. Bd. of Educ. of Salt Lake City*, 60 P. 1013 (Utah 1900) (upholding mandatory smallpox vaccination for students).

⁹⁷ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

⁹⁸ The Revised Laws of that Commonwealth [of Massachusetts], c. 75 § 137, provide that the board of health of a city or town if, in its opinion, it is necessary for the public health or safety shall require and enforce the vaccination and revaccination of all the inhabitants thereof and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit five dollars.

Id. at 12 (quoting MASS. GEN. LAWS ch. 75, § 137 (1902) (current version at MASS. GEN. LAWS ch. 111, § 181 (2004))).

⁹⁹ *Id.* at 12-13.

¹⁰⁰ *Id.* at 13-14.

preme Judicial Court of Massachusetts overruled Jacobson's exceptions and sentenced him to pay a fine of five dollars.¹⁰¹

On appeal, the Supreme Court of the United States upheld the verdict, holding that "[i]t is within the police power of a state to enact a compulsory vaccination law, and it is for the legislature, and not for the courts, to determine in the first instance whether vaccination is or is not the best mode for the prevention of smallpox and the protection of the public health."¹⁰² The Court defined police power as "a power which the State did not surrender when becoming a member of the Union under the Constitution."¹⁰³ The Court found that when the Board of Health adopted the regulation, smallpox was prevalent in Cambridge and the disease was spreading.¹⁰⁴ Because state police powers include regulations created to protect the public health,¹⁰⁵ and the public health was threatened by smallpox, both the Massachusetts statute and the regulation of the Board of Health were valid, and the Board of Health acted within its state police powers to compel vaccination.¹⁰⁶

Jacobson offered the opinions of medical professionals who felt that vaccination had "little or no value . . . as a means of preventing the spread of smallpox."¹⁰⁷ Stating that the value and efficacy of smallpox vaccine was a concern of the Massachusetts legislature, and not the judiciary, the Court did not consider Jacobson's opinions.¹⁰⁸

The fact that the belief [that vaccines are an effective means to prevent and control the spread of smallpox] is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action; for what the people believe is for the common welfare must be accepted as tending to promote the common welfare, whether it does in fact or not. Any other basis would conflict with the spirit of the Constitution, and would sanction measures opposed to a republican form of government. While we do not decide and cannot decide that vaccination is a preventive of smallpox, we take judicial notice of the fact that this is the common belief of the people of the State, and with this fact as a foundation we hold that the statute in question is a health law, enacted in a reasonable and proper exercise of the police power.¹⁰⁹

¹⁰¹ *Id.* at 14.

¹⁰² *Id.* at 11-12.

¹⁰³ *Jacobson*, 197 U.S. at 25.

¹⁰⁴ *Id.* at 27.

¹⁰⁵ *Id.* at 25.

¹⁰⁶ *Id.* at 28.

¹⁰⁷ *Id.* at 30.

¹⁰⁸ *Id.* at 30-31.

¹⁰⁹ *Jacobson*, 197 U.S. at 35 (quoting *Viemeister v. White*, 179 N.Y. 235, 241(1904)).

Finally, the Court held that a minority of citizens cannot defy the decisions of their legislature, when the legislature acts “in good faith for all,” if the minority’s actions would endanger the welfare of the entire community.¹¹⁰ Holding that the safety and health of the people of Massachusetts are the responsibility of the state, and that they are not ordinarily concerns of the national government, the Court ruled that the Massachusetts statute did not violate the Federal Constitution.¹¹¹

B. *Limits of State Police Powers to Compel Vaccination*

Although the Court ruled that the mandatory vaccination statute fell within the state police powers of Massachusetts, the Court did proscribe limits to such power:

[I]t might be that an acknowledged power of a local community to protect itself against an epidemic threatening the safety of all, might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.¹¹²

Thus the Court set forth a reasonableness test for mandatory vaccination statutes. In *Jacobson*, the vaccination program was reasonable in light of the prevalence of smallpox in Cambridge, and the Board of Health had no motivation, other than to protect the public’s health, when it enacted the mandatory vaccination program.¹¹³

The Court also held that courts may strike down legislation designed to protect the general welfare only when it “has no real or substantial relation to [public health, morals, or safety] or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law.”¹¹⁴ The Court found that the statute could not “be affirmed to be, beyond question, in palpable conflict with the Constitution.”¹¹⁵ Finally, the Court repeated that state police powers have limits, and can be encroached upon by the judiciary, namely when the police powers are used in an “arbitrary and oppressive” manner.¹¹⁶

¹¹⁰ *Id.* at 37-38.

¹¹¹ *Id.* at 38.

¹¹² *Id.* at 28.

¹¹³ *Id.* at 31.

¹¹⁴ *Id.*

¹¹⁵ *Jacobson*, 197 U.S. at 31.

¹¹⁶ *Id.* at 38.

III. IF HEARD IN 2004, THE OUTCOME OF *JACOBSON* WOULD BE DIFFERENT

Smallpox was eradicated seventy-five years after Jacobson was decided,¹¹⁷ making mandatory smallpox vaccinations no longer a reasonable measure to protect the public's health. In response, CDC halted mass smallpox vaccination in the United States in 1971.¹¹⁸ However, the threat of terrorists using smallpox as a weapon may make the use of the vaccine a reasonable measure.

A. *Smallpox Eradication No Longer Necessitates Mandatory Smallpox Vaccination*

If Mr. Jacobson were told to roll up his sleeve and receive a smallpox vaccination in 2005, he would be able to refuse. In *Jacobson*, Justice Harlan wrote that a state's police powers "might be exercised . . . in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons."¹¹⁹ Now that smallpox is eradicated, there is no need to vaccinate against it in any country. The probability of contracting smallpox is zero, so there is no possibility of infection. Therefore, the burdens of adverse events associated with the vaccine outweigh the benefits of immunity to the disease conferred by the vaccine.¹²⁰ There is no reasonable basis to compel someone to receive a potentially harmful immunization when the disease against which the immunization is directed no longer exists. Such use of a state's police power goes, as Justice Harlan wrote, "so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere."¹²¹ If

¹¹⁷ The World Health Org., *supra* note 11.

¹¹⁸ Ctr. For Disease Control & Prevention, U.S. Dep't of Health, Educ., & Welfare, *Vaccination Against Smallpox in the United States—a Reevaluation of the Risks and Benefits*, 20 MORBIDITY AND MORTALITY WKLY. REP. 339, 339 (1971) [hereinafter CDC, *Vaccination Against Smallpox—Reevaluation*].

¹¹⁹ *Jacobson*, 197 U.S. at 28.

¹²⁰ When announcing the decision to halt smallpox vaccination, CDC stated that "the probability of contracting smallpox is so small that the risk of complications from the vaccination outweighs the benefits derived from it. For this reason, non-selective vaccination of the public is no longer justifiable." CDC, *Vaccination Against Smallpox—Reevaluation*, *supra* note 118, at 339. Smallpox vaccination was thus halted in the United States in 1971, nine years before global eradication of the disease was certified, and while smallpox was still infecting individuals in other parts of the world.

¹²¹ *Jacobson*, 197 U.S. at 28.

Mr. Jacobson were to come before the Supreme Court today, he would not be forced to receive the vaccine, or to pay his five dollar fine.

B. *Smallpox Vaccination and Bioterrorism*

The only justification for mass smallpox vaccination today is for protection from bioterrorist attacks.¹²² Smallpox was perhaps the first biological agent used in warfare. In the Fourteenth Century, Tartar forces catapulted the corpses of smallpox victims into enemy towns to weaken and kill their forces.¹²³ During the French and Indian Wars, soldiers intentionally distributed blankets that were used by smallpox patients to Native Americans, causing an epidemic that killed over half of infected tribes.¹²⁴ Biological agents have recently been used against the United States, when anthrax was mailed to residents of Florida, Nevada, and New York, and members of Congress.¹²⁵ In December 2002, President George W. Bush announced a national smallpox vaccination program, which stated that “[a]lthough there is no reason to believe that smallpox presents an imminent threat, the attacks of September and October, 2001 have heightened concern that terrorists may have access to the [smallpox] virus and attempt to use it against the American public.”¹²⁶ The plan called for the voluntary vaccination of 500,000 health workers by mid-January 2003, and for voluntary vaccination of up to 10,000,000 health and emergency workers in the following ninety days.¹²⁷ By July 18, 2003, only 37,971 civilians were vaccinated and the plan has been described as “stalled.”¹²⁸

¹²² See generally Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program*, MORBIDITY & MORTALITY WKLY. REP. RECOMMENDATIONS & REPS., Apr. 4, 2003, at 1-16 [hereinafter CDC, *Pre-Event Vaccination*]. This report was issued to update existing CDC smallpox guidelines in response to the terrorist attacks of 2001. *Id.*

¹²³ Ken Alibek, *Smallpox: A Disease and a Weapon*, 8S2 INT’L J. INFECTIOUS DISEASES S3, S4 (2004).

¹²⁴ *Id.*

¹²⁵ See Sheryl Gay Stolberg & Alison Mitchell, *Letter Containing Anthrax Sent to U.S. Senate Leader*, N.Y. TIMES, Oct. 16, 2001, at A1.

¹²⁶ Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Protecting Americans: Smallpox Vaccination Program*, at <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/vaccination-program-statement.pdf> (last visited Oct. 25, 2004) [hereinafter CDC, *Protecting Americans*].

¹²⁷ William J. Bicknell & Kenneth D. Bloem, *Smallpox and Bioterrorism: Why the Plan to Protect the Nation is Stalled and What to Do*, 85 CATO INST. BRIEFING PAPERS 1, 2 (2003), available at <http://www.cato.org/pubs/briefs/bp-085es.html> (last visited Oct. 25, 2004).

¹²⁸ *Id.* at 1-2.

Smallpox strains are officially contained in only two repositories, the WHO Collaborating Centre for Smallpox & Other Poxvirus Infections at CDC in Atlanta, Georgia, and the WHO Collaborating Centre for Orthopoxvirus Diagnosis and Repository for Variola Virus Strains and DNA at the State Research Centre of Virology and Biotechnology in Koltosovo, Novosibirsk Region, Russian Federation.¹²⁹ The United States is concerned that Iran, Iraq, Libya, and North Korea also have smallpox strains that are being used to create biological weapons.¹³⁰ A United States intelligence review also included France in the list of countries possessing undeclared stocks of smallpox virus, but France denied this allegation, claiming that its research used authorized animal samples.¹³¹ This same intelligence review also indicated that al Qaeda was interested in obtaining smallpox.¹³² The possibility that smallpox could fall into the hands of terrorist organizations is obviously cause for concern. The proper approach to address this concern is a topic of debate.

Public health experts disagree about the likelihood of a smallpox attack¹³³ and the need to vaccinate before such an attack occurs. Some feel that the risk and consequences of a smallpox attack, using a weaponized virus developed by the former Soviet Union, are sufficiently great so as to outweigh the potential costs and injuries associated with the smallpox vaccine.¹³⁴ Others feel that the “potential for biological terrorism is real (i.e., greater than zero), but very low, and in almost any foreseeable attack the number of deaths is likely to be low (as evidenced in the only real biological attacks to date [i.e., the anthrax attacks], in which between zero and five people died).”¹³⁵ Others have used even stronger words: “The whole bioterrorism initiative and what it’s doing to public health is a cancer, and it’s hollowing out public health from within . . . This is a catastrophe for

¹²⁹ Jean Pascal Zanders, *Addressing the concerns about smallpox*, 8S2 INT’L J. OF INFECTIOUS DISEASES S9, S10 (2004).

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ See generally John Mintz, *Technical Hurdles Separate Terrorists From Biowarfare*, WASH. POST, Dec. 30, 2004, at A1.

¹³⁴ Bicknell & Bloem, *supra* note 127, at 2.

¹³⁵ George Annas, *Puppy Love: Bioterrorism, Civil Rights, and Public Health*, 55 FLA. L. REV. 1171, 1177 (2003) [hereinafter Annas, *Puppy Love*].

American public health.”¹³⁶ Some experts have concluded that “[i]t is impossible to estimate how real this [smallpox] threat is.”¹³⁷

The main difference between these views is the perceived probability of a smallpox attack, and the amount of damage such an attack would cause. This would present a troubling issue for a court to decide, namely whether it is reasonable for states to require smallpox vaccination. On one hand, the United States stopped routine smallpox vaccination even before the disease was eradicated, which shows that smallpox was not considered a public health threat even while it was still known to exist naturally. The use of the vaccine, and its associated risks, would, therefore, be inappropriate, since the disease no longer exists naturally and there is no evidence that any terrorist group truly does possess smallpox. On the other hand, a smallpox attack could cause fear and panic, and could lead to greater societal harm than that caused by the infection itself.¹³⁸ By immunizing appropriate members of the population, a state government could prevent some of this panic. WHO Director-General Gro Harlem Brundtland stated that “[t]he risk of adverse events [from smallpox vaccination] is sufficiently high that mass vaccination is not warranted if there is no or little real risk of exposure.”¹³⁹ Therefore, WHO guidelines recommend against the vaccination of entire populations or large groups of emergency personnel.¹⁴⁰

Further complicating this analysis is the state of the vaccine itself. In 2002, Aventis-Pasteur, a French vaccine manufacturer, donated 85 million doses of smallpox vaccine to the United States.¹⁴¹ Although it was tested and found to be “still good,” the donated material is 40 years old.¹⁴² The United States also maintains a stockpile of Dryvax, which is the last smallpox vaccine produced domestically.¹⁴³ Manufacture of Dryvax was discontinued in 1981, therefore, all of the Dryvax doses are at least twenty-four

¹³⁶ Stephen Smith, Health Science, *Anthrax vs. the Flu: As State Governments Slash Their Public Health Budgets, Federal Money is Pouring in for Bioterror Preparedness*, BOSTON GLOBE, July 29, 2003, at C1.

¹³⁷ Riccardo Wittek, *Could smallpox come back?*, 8S2 INT’L J. OF INFECTIOUS DISEASES S1, S1 (2004).

¹³⁸ Arguably the greatest advantage of biological weapons is their ability to cause mass panic. “[E]ven if a biological attack kills only a relatively small number, it is likely to generate panic. This shredding of the fabric of the community and exposure of society’s vulnerability, perhaps on a global scale, is the incentive for committing such heinous crimes.” Barry Kellman, *Biological Terrorism: Legal Measures for Preventing Catastrophe*, 24 HARV. J.L. & PUB. POL’Y. 417, 429 (2000).

¹³⁹ Zanders, *supra* note 129, at S12.

¹⁴⁰ *Id.*

¹⁴¹ Ceci Connolly, *Aventis to Donate Smallpox Vaccine*, WASH. POST, Mar. 30, 2002, at A2.

¹⁴² *Id.*

¹⁴³ Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Vaccinia (Smallpox) Vaccine*, MORBIDITY & MORTALITY WKLY. REP. RECOMMENDATIONS & REPS., June 22, 2001, at 3 (2001) [hereinafter CDC, *Smallpox Vaccine*].

years old.¹⁴⁴ Because these vaccines have not been used for so long, and because they are so old, the safety and efficacy of the material is unknown, making it difficult to accurately determine the burden of vaccination. For instance, the manufacturer of Dryvax recently added a “black box” warning, approved by the Food and Drug Administration (“FDA”), to Dryvax, linking the vaccine to acute myopericarditis, which is inflammation of the heart and its surrounding sac.¹⁴⁵ A recent clinical trial showed that one in 145 people who received the vaccine developed myopericarditis, while a Department of Defense vaccination program found 1.2 cases per 10,000 individuals vaccinated.¹⁴⁶ “These cardiac adverse events represented an important and, apparently, previously under-recognized complication of [smallpox] vaccination,”¹⁴⁷ and it is unclear why vaccine recipients are now developing myopericarditis. One possible explanation is the age of the Dryvax material.

Forced smallpox vaccination would not likely be upheld because such vaccination is unreasonable. First, the likelihood of a smallpox attack is currently unknown because no one knows for sure if any terrorist group or enemy state actually has weaponized smallpox. Second, the impact of a smallpox attack is unclear because the disease is not transmitted from one person to another until the onset of rash and skin lesions.¹⁴⁸ At this point the infected individual is obviously ill, and is in too much pain to remain sufficiently ambulant to spread the disease.¹⁴⁹ Therefore, a smallpox attack may not lead to a rapid spread of the disease, and limits the possibility of “suicide bombers” purposely infecting themselves and spreading the disease by walking through crowded areas.¹⁵⁰ Finally, the extreme age of the current vaccine supply precludes perfect information regarding the safety of the vaccine. Previously unseen adverse events associated with this old vaccine underscore this safety concern. It is, therefore, unreasonable to force individuals to be immunized with a vaccine of unknown safety, in order to protect against an attack that may never occur, against a disease that no longer naturally exists and can be effectively contained by quarantine and vaccina-

¹⁴⁴ *Id.* at 21.

¹⁴⁵ See Wall St. J. Online, *Wyeth To Add Warning On Its Smallpox Vaccine*, available at http://online.wsj.com/article/0,,BT_CO_20041112_009808,00.html (last visited Nov. 15, 2004).

¹⁴⁶ SignOnSanDiego, *Warning Links Dryvax, Heart Inflammation*, available at <http://www.signonsandiego.com/news/health/20041112-1457-dryvax-warning.html> (last visited Oct. 14, 2005).

¹⁴⁷ Acambis, *ACAM2000 clinical trials update*, available at <http://www.acambis.com/default.asp?id=782> (last visited Oct. 13, 2005).

¹⁴⁸ See Henderson & Moss, *supra* note 10, at 77-78.

¹⁴⁹ *Id.* at 76; see Zanders, *supra* note 129, at S10.

¹⁵⁰ Zanders, *supra* note 129, at S10.

tion after an attack. Because forced smallpox vaccination is unreasonable, such a policy does not withstand the rule set forth in *Jacobson*.

IV. MANDATORY VACCINATION AND UNCONSTITUTIONAL CONDITIONS

“The problem of unconstitutional conditions arises whenever a government seeks to achieve its desired result by obtaining bargained-for *consent* of the party whose conduct is to be restricted.”¹⁵¹ This doctrine has been described in two different frameworks, which are applied below to the issue of mandatory vaccinations.

A. *The Doctrine of Unconstitutional Conditions—Two Conceptual Frameworks*

1. Pareto Superiority Test

The doctrine of unconstitutional conditions has been explained by Prof. Richard Epstein as an adaptation of the Pareto superiority test, which holds that “if no person in state A is worse off than he was in state B, and at least one person is better off in state A than he was in state B, then state A must be judged as superior to state B.”¹⁵² The baseline for the Pareto superiority test is the status quo ante (or “state B”), so when individuals reject a bargain or grant, they are no worse off than they were before, as they have not changed their position.¹⁵³ This test can be applied to bargains or grants between individuals, or between individuals and the state. In the latter case, the state is treated as “a single person that knows its own preferences, measured against the same baseline of the status quo ante.”¹⁵⁴ Individuals who agree to accept the bargain do so because they are better off than they were before the bargain. As Prof. Epstein observes, “Either way, they are not in a position to complain.”¹⁵⁵

¹⁵¹ Richard A. Epstein, *The Supreme Court 1987 Term: Unconstitutional Conditions, State Power, and the Limits of Consent*, 102 HARV. L. REV. 5, 7 (1988) (emphasis in original).

¹⁵² *Id.* at 9.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

Assuming that individuals only accept Pareto superior bargains, bargains improve overall social welfare.¹⁵⁶ To assure the benefit of the bargain really does enhance social welfare, the Pareto superior test seeks to enforce bargains only when two criteria are met.¹⁵⁷ First, the bargain must create joint gains for the contracting parties.¹⁵⁸ Second, the bargain must respect the interests of third parties who are not parties to the bargain.¹⁵⁹ The first prong is satisfied by refusing to enforce bargains induced by force and fraud.¹⁶⁰ The second prong is satisfied by refusing to enforce bargains that use or threaten to use coercion or fraud against third parties.¹⁶¹ Therefore, an unconstitutional condition is established under the Pareto superiority test when the bargain is reached under force, fraud, or coercion.

2. Two-Part Effects Test

The unconstitutional conditions doctrine has also been explained by Prof. Lynn Baker as a two-part effects test.¹⁶² Under this framework, the court first determines “whether the condition at issue impinges on, burdens, or penalizes the exercise of a constitutional right.”¹⁶³ If the court determines that a constitutional right has been burdened, then the court inquires if the condition is justified by a compelling state interest.¹⁶⁴ If the court determines that a constitutional right has not been burdened, then the court inquires if the condition is justified by a rational basis.¹⁶⁵

In applying this test, the Court has *never* found the State’s interest sufficiently compelling to justify a condition that burdens a constitutional right. The Court has *always* been able to find a rational basis for conditions that impose no such burden, however. Thus, from the State’s perspective, the ‘compelling state interest’ standard is difficult in theory and fatal in fact, while the ‘rational basis’ requirement is minimal in theory and virtually nonexistent in fact.¹⁶⁶

¹⁵⁶ *Id.*

¹⁵⁷ *See* Epstein, *supra* note 151, at 14.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *See* Lynn A. Baker, *The Prices of Rights: Towards a Positive Theory of Unconstitutional Conditions*, 75 CORNELL L. REV. 1185, 1193 (1990).

¹⁶³ *Id.* at 1202.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 1202-03 (citations omitted) (emphasis in original).

Therefore, the key to successfully establishing an unconstitutional condition, within the framework of this effects test, is proof that a constitutional right has been impinged, burdened, or penalized.

B. *Mandatory Smallpox Vaccination as an Unconstitutional Condition*

There are two categories of unconstitutional conditions: “1) conditions that present a choice of actions; and 2) conditions that automatically disqualify persons who possess some immutable characteristic.”¹⁶⁷ Mandatory vaccination for access to public schools is a possible example of the first category. This section contemplates the constitutionality of mandatory smallpox vaccination for public school students. Such a program would force parents to choose between not sending their children to school and vaccinating their children for a disease which no longer exists. In some states, parents also face criminal penalties for not sending their children to school, effectively requiring parents to vaccinate their children or go to jail.¹⁶⁸ Such a requirement for smallpox vaccination would be an unconstitutional condition under either the Pareto superiority test or the two-part effects test.

1. Pareto Superiority Test

The Pareto superiority test has been used to explain several U.S. Supreme Court decisions. In *Sherbert v. Verner*,¹⁶⁹ the appellant, a member of the Seventh-day Adventist Church, was terminated from her job because she refused to work on Saturday, the Sabbath Day of her faith.¹⁷⁰ The appellant was also denied unemployment benefits because South Carolina law stated that a claimant is ineligible for unemployment benefits if “he has failed, without good cause . . . to accept available suitable work when offered him by the employment office or the employer.”¹⁷¹ Thus the appellant

¹⁶⁷ *Id.* at 1189.

¹⁶⁸ See, e.g., *Allison v. Merck*, 878 P.2d 948, 954 (Nev. 1994). More recently, forty-one parents and guardians in Washington, D.C. were charged with violating a school attendance law because their children’s vaccinations were not up to date. These children were therefore barred from school, bringing their parents in violation of the attendance law. In 2003, ninety-eight cases were brought for a range of violations of the school attendance law, resulting in two parents being sentenced to three days in jail after failing a deferred sentencing program. See Manny Fernandez, *Parents of D.C. Students Without Shots Sent to Court*, WASH. POST, Oct. 30, 2004, at B1.

¹⁶⁹ *Sherbert v. Verner*, 374 U.S. 398 (1963).

¹⁷⁰ *Id.* at 399.

¹⁷¹ *Id.* at 401 (quoting S.C. Code Ann. § 68-114(3) (1962)).

was forced to make a difficult choice: continue to practice the tenets of her religion and forego employment opportunities and unemployment benefits, or violate her religious beliefs and agree to work on the Sabbath in order to find a job or receive unemployment. The Court ruled in the appellant's favor, finding that the elimination of the unemployment benefits was a form of coercion.¹⁷² In his opinion for the Court, Justice Brennan wrote:

Here not only is it apparent that appellant's declared ineligibility for benefits derives solely from the practice of her religion, but the pressure upon her to forego that practice is unmistakable. The ruling forces her to choose between following the precepts of her religion and forfeiting benefits, on the one hand, and abandoning one of the precepts of her religion in order to accept work, on the other hand. Governmental imposition of such a choice puts the same kind of burden upon the free exercise of religion as would a fine imposed against appellant for her Saturday worship.

Nor may the South Carolina court's construction of the statute be saved from constitutional infirmity on the ground that unemployment compensation benefits are not appellant's "right" but merely a "privilege." It is too late in the day to doubt that the liberties of religion and expression may be infringed by the denial of or placing of conditions upon a benefit or privilege.¹⁷³

In *Sherbert*, South Carolina did not have to provide any benefits. However, once the state chose to provide such benefits, "it cannot condition them upon the willingness of people to work in ways that contravene their religious beliefs."¹⁷⁴ This coercion violates the Pareto superiority test because it forces members of certain religious groups to make a sacrifice not required by all citizens of the state. Those who place a higher value on their religious beliefs than do other citizens of the same religion will not be able to receive unemployment benefits. Thus their religion acts as a fine against their available government-provided benefits. Even the Seventh-day Adventists who place a higher value on the receipt of benefits than on religion will be "fined," namely by abridging their ability to practice their religion. Therefore, any bargain, in the Pareto superior sense, reached by unemployed Seventh-day Adventists and the State of South Carolina, under the laws at issue in *Sherbert*, would not necessarily put Seventh-day Adventists in a superior position relative to the status quo ante of non-Seventh-day Adventists and would only be reached through coercion.

In *Harris v. McRae*,¹⁷⁵ the Supreme Court ruled that the Medicaid program did not have to fund abortions. In September 1976, Congress passed the Hyde Amendment, which prohibited the use of federal funds to reimburse the cost of abortions under the Medicaid program except under cer-

¹⁷² Epstein, *supra* note 151, at 81.

¹⁷³ *Sherbert*, 374 U.S. at 404 (citations omitted).

¹⁷⁴ Epstein, *supra* note 151, at 82.

¹⁷⁵ *Harris v. McRae*, 448 U.S. 297 (1980).

tain conditions, such as rape or incest.¹⁷⁶ However, the Hyde Amendment permitted the use of Medicaid funds to pay for costs associated with childbirth.¹⁷⁷ A class of pregnant women who received Medicaid benefits brought suit, claiming that the Hyde Amendment was unconstitutional because it denied funding to indigent women who could not otherwise afford an abortion.¹⁷⁸ The Court held that the Hyde Amendment was constitutional, because the Amendment did not prevent indigent women from choosing to terminate pregnancies. Justice Stewart wrote that “[t]he Hyde Amendment . . . places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy, but rather, by means of unequal subsidization of abortion and other medical services, encourages alternative activity deemed in the public interest.”¹⁷⁹ Although women have a protected right to seek abortions under *Roe v. Wade*,¹⁸⁰ Justice Stewart observed that:

[I]t simply does not follow that a woman's freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices. . . . [A]lthough government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those not of its own creation. Indigency falls in the latter category. The financial constraints that restrict an indigent woman's ability to enjoy the full range of constitutionally protected freedom of choice are the product not of governmental restrictions on access to abortions, but rather of her indigency.¹⁸¹

Justice Stewart's analysis follows the Pareto superiority test. A Medicaid program that includes the limitations provided by the Hyde Amendment makes indigent pregnant women who wish to terminate their pregnancies no worse off than they would be without the program. Therefore, the status quo ante is preserved for these women. Because such women are still free to terminate their pregnancies, albeit without federal funding, they are not asked to give up the rights provided by *Roe v. Wade*. Therefore, there is no coercion to forego a constitutional right upon which receipt of other Medicaid benefits are conditioned.

One could argue that because the Hyde Amendment covers the costs of childbirth but not abortion, indigent women who cannot afford an abortion procedure are thus coerced into giving birth. The problem with this argument is that without any Medicaid program, pregnant women who could not afford an abortion would still have to give birth. The Hyde Amendment can be viewed as a subsidy to indigent mothers, allowing poor

¹⁷⁶ *Id.* at 302.

¹⁷⁷ *Id.* at 303.

¹⁷⁸ *See id.*

¹⁷⁹ *Id.* at 315.

¹⁸⁰ *Roe v. Wade*, 410 U.S. 113, 153 (1973).

¹⁸¹ *Harris*, 448 U.S. at 316.

women who have a child to be reimbursed for their childbirth costs. Those who choose to terminate their pregnancies do not receive any federal subsidy, but are free to have an abortion and to seek financial assistance from other sources. Therefore, all women may still choose to have a child, or to have an abortion. Such a scheme is constitutional because the Medicaid program was not created to cover all health services, but only those described in a legislatively approved plan, thus Congress can decide which medical procedures are covered under the program.¹⁸² Because this limited Medicaid program is an improvement for indigent pregnant women compared to their status quo ante, and they are not coerced to forfeit a constitutional right, the Hyde Amendment does not violate the doctrine of unconstitutional conditions.

Mandatory smallpox vaccinations fail the Pareto superiority test. First, vaccinating individuals for a disease which no longer exists fails to improve either party's position. Absent a terrorist threat, smallpox vaccinations expose children to potential adverse events and for protection against an infectious agent that no longer presents a danger. One could argue that in return for complying with the vaccination requirement, children receive the benefit of public education, which improves their position. However, this involves the same trade-offs seen in *Sherbert*, where the appellant was forced to choose between practicing her religion and receiving unemployment benefits. Here, parents are forced to choose between access to public education for their children and the potential injuries that could arise from vaccinations that provide no protection against extant diseases and are, therefore, unreasonable.¹⁸³ In order to receive public education, parents must be willing to accept the risk of unnecessary injury to their children. Just as the appellant in *Sherbert* was not forced to choose between free exercise of religion and employment, parents cannot be forced to choose between public education and the ability to forego unreasonable vaccinations.¹⁸⁴ It also does not appear that mandatory smallpox vaccinations put public schools in a better position than the status quo ante. Because smallpox has not presented a danger for decades, requiring vaccination does not protect the schools' students from any present threat.

Second, mandatory school attendance laws in effect make vaccination mandatory; if parents do not vaccinate their children then the children cannot go to school, which eventually leads to the threat of jail time for par-

¹⁸² See *id.* at 308.

¹⁸³ Smallpox vaccinations are unreasonable because they do not provide protection against diseases that present a current threat. See *supra* Part III.A.

¹⁸⁴ *Sherbert*, 374 U.S. at 404; see also *supra* Part III.A.

ents.¹⁸⁵ Parents are thus forced and coerced into vaccinating their children, exposing their children to potential injury or death, with no tangible medical benefit. Mandatory vaccinations are distinct from *Harris v. McRae* because, although the Hyde Amendment created an incentive for indigent pregnant women to give birth instead of terminating their pregnancies, it did not force or coerce them to give up a constitutional right to receive a benefit, and there was no threat of jail for women who elected to terminate their pregnancies. Mandatory smallpox vaccinations would force parents of public school students to choose between foregoing a constitutional right, namely the right to decline unreasonable vaccinations, in order to receive the benefit of public education, or to go to jail. This use of force and coercion to ensure the state gets the bargain it wants is unenforceable under the Pareto superiority test, thus the bargain represents an unconstitutional condition.

2. Two-Part Effects Test

The two-part effects test has been used to explain the result in *Sherbert v. Verner* and other public assistance cases.¹⁸⁶ The unemployment benefits statute at issue in *Sherbert* can be described as “increas[ing] . . . the price of exercising a constitutional right.”¹⁸⁷ Seventh-day Adventists who chose to follow their religious beliefs and thus lost their jobs for opting not to work on Saturdays were forced to forego unemployment benefits.¹⁸⁸ Therefore, Seventh-day Adventists were forced to bear a burden not shared by practitioners of other faiths, and to exercise their religion “at a higher price than similarly situation persons.”¹⁸⁹ Because the free exercise of religion is guaranteed by the Constitution,¹⁹⁰ the unemployment condition in *Sherbert* burdened the constitutional rights of Seventh-day Adventists. Under the two-part effects test, if a constitutional right is burdened, the state must establish a compelling interest to uphold the statute.¹⁹¹ Because there is no compelling state interest in denying unemployment benefits to Sev-

¹⁸⁵ See *supra* note 168. Smallpox vaccination has historically been associated with coercive measures designed to enforce mass immunization. See generally James Colgrove, *Between Persuasion and Compulsion: Smallpox Control in Brooklyn and New York, 1894-1902*, 78 BULL. OF THE HIST. OF MED. 349 (2004).

¹⁸⁶ See Baker, *supra* note 162, at 1250.

¹⁸⁷ *Id.*

¹⁸⁸ *Sherbert*, 374 U.S. at 401.

¹⁸⁹ Baker, *supra* note 162, at 1250.

¹⁹⁰ U.S. CONST. amend. I.

¹⁹¹ Baker, *supra* note 162, at 1202.

enth-day Adventists who will not work on Saturdays for religious reasons, the South Carolina statute was correctly struck down.

The two-part effects test has also been used to explain the result in *Harris v. McRae* and other abortion funding cases.¹⁹² In *Harris*, indigent pregnant women were denied funding from Medicare to obtain abortions.¹⁹³ The *Harris* plaintiffs sought to frame the issue such that “it should be . . . impermissible for a state to provide medical benefits to women during pregnancy on the condition that they not have an elective abortion.”¹⁹⁴ However, the Supreme Court looked at the issue “in terms of the cost to the individual exercising the constitutional right.”¹⁹⁵ The constitutional right at issue was the right to terminate a pregnancy during the first trimester.¹⁹⁶ Although Medicare would not fund abortion procedures, this did not increase the cost of exercising this right. The indigent women who were qualified to receive Medicare funding and who decided to terminate their pregnancies “were simply left to pay the market price for that medical service,”¹⁹⁷ which is the same price paid by similarly situated women with higher incomes. As Justice Stewart wrote in *Harris*, “[A]lthough government may not place obstacles in the path of a woman’s exercise of her freedom of choice, it need not remove those not of its own creation. Indigency falls into the latter category.”¹⁹⁸

Providing Medicare funding for abortion procedures would decrease the cost of exercising a right, but denial of such funding does not increase the cost of exercising this right. Therefore, a constitutional right was not impinged or burdened in *Harris*, and under the two-part effects test the government must merely show a rational basis for the statute in question.¹⁹⁹ In *Harris*, such a rational basis would be protecting potential human life.²⁰⁰ Thus, under the two-part effects test, a Medicare program can opt not to fund abortion procedures, and *Harris v. McRae* was correctly decided.

As already shown, mandatory smallpox vaccination is not reasonable, and it is, therefore, unconstitutional under *Jacobson*.²⁰¹ Mandatory smallpox vaccination for public school students would, therefore, increase the cost of exercising a constitutional right. Although parents could theoretically decide to forego the immunization for their children, the potential threat of

192 *Id.* at 1228-32.

193 *Harris*, 448 U.S. at 303.

194 Baker, *supra* note 162, at 1230.

195 *Id.* at 1231.

196 *Id.*

197 *Id.*

198 *Harris*, 448 U.S. at 316.

199 Baker, *supra* note 162, at 1202-03.

200 *Harris*, 448 U.S. at 324-25.

201 *See supra* Part III.A.

jail time²⁰² is obviously a heavy price to pay to exercise the right to decline unreasonable vaccinations. Some families could afford to send their children to private schools or to home school, but this also increases the costs of exercising a constitutional right in the form of tuition costs not incurred by parents of public school children, or foregone wages by parents who choose to home school instead of working. Thus, under the two-part effects test for unconstitutional conditions, a state must show a compelling interest to uphold mandatory vaccination.²⁰³ Because there is no reasonable basis for vaccination, there can be no compelling interest and mandatory vaccination is an unconstitutional condition under the two-part effects test.

Alternatively, if mandatory vaccination is somehow determined to be reasonable,²⁰⁴ and, therefore, constitutional under *Jacobson*, the state must merely show a rational basis to uphold the vaccinations. If compelled use of the vaccine is reasonable, then the state obviously has a rational basis for its use. The two-part effects test thus results in a circular logic in this instance. All that needs to be shown under the test is that a constitutional right has been burdened, and under *Jacobson* the right to refuse vaccination is constitutional only when the rationale for the vaccination is unreasonable.²⁰⁵ This reduces the entire two-part effects test analysis into a reasonable basis test.

V. MANDATORY POLIO VACCINATION IS ANALOGOUS TO MANDATORY SMALLPOX VACCINATION

Once polio eradication is certified, polio vaccinations will be analogous to smallpox vaccinations, as both vaccines will cover diseases that no longer infect the global population because neither exists as a wild-type virus. However, both diseases could potentially be used as weapons of terrorism, making continued use of the vaccines a potential necessity. This Part discusses the possible use of poliovirus as a weapon, and makes recommendations for future use of polio and smallpox vaccines.

A. *Poliovirus as a Biological Weapon*

As with smallpox, the best rationale for continued polio vaccination is protection from terrorist attack.²⁰⁶ Cessation of polio vaccination would

²⁰² See *supra* note 168.

²⁰³ Baker, *supra* note 162, at 1202.

²⁰⁴ See *infra* Part V.A.

²⁰⁵ *Jacobson*, 197 U.S. at 28. See also *supra* Part II.B.

²⁰⁶ Roland W. Sutter et al., *The Role of Routine Polio Immunization in the Post-Certification Era*, 82 BULL. OF THE WORLD HEALTH ORG. 31, 32 (2004).

create “a large non-immune population susceptible to potential agents for bioterrorism.”²⁰⁷ Although there is no guarantee that biological attacks will ever occur, and the risk of such attack is considered by many experts to be low,²⁰⁸ polio is currently indigenous in countries like Afghanistan and Egypt,²⁰⁹ where terrorists likely exist. It would, therefore, be easy for terrorist groups to obtain and save poliovirus for future use once polio vaccine administration is stopped.²¹⁰ Discontinuing the use of polio vaccines could, therefore, make the non-immunized group a strong target for biological attack. The effect of such an attack on a non-immunized population would obviously be a public health crisis.

However, even if such an attack does occur, there is no guarantee that vaccine coverage will be effective. Terrorists could develop weaponized versions of smallpox or polio which are sufficiently different from the antigenic material in the vaccine so as to render the vaccination ineffective.²¹¹ For instance, particular surface proteins in the viral capsule of polio²¹² and smallpox²¹³ are the epitopes to which the vaccines are directed; by changing these surface proteins, terrorists could bypass the effective range of the

²⁰⁷ *Id.*

²⁰⁸ See, e.g., CDC, *Pre-Event Vaccination*, *supra* note 122, at 3 (“[A] risk for smallpox occurring as a result of a deliberate release by terrorists exists; however, this risk is low, and the population at risk for such an exposure cannot be determined.”); Annas, *Puppy Love*, *supra* note 135, at 1177 (“[T]he potential for biological terrorism is real (i.e., greater than zero), but very low.”); John Mintz & Joby Warrick, *U.S. Unprepared Despite Progress, Experts Say*, WASH. POST, Nov. 8, 2004, at A1 (“Because of the technical difficulties in creating such [vaccine-resistant biological] weapons, [experts] reckon the chances of a devastating attack are currently small.”); Ctrs. For Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *What CDC is Doing to Prevent the Public from Smallpox*, available at <http://www.bt.cdc.gov/agent/smallpox/prep/cdc-prep.asp> (last visited Sept. 8, 2005) (“The risk for smallpox occurring as a result of a deliberate release by terrorists is not known, but is considered very low.”); CDC, *Protecting Americans*, *supra* note 126 (When initiating his smallpox vaccination program, the President stated that “there is no reason to believe that smallpox presents an imminent threat.”).

²⁰⁹ Heymann, *supra* note 4, at 1.

²¹⁰ Collecting all the existing stocks of poliovirus is a difficult task because unlike smallpox, poliovirus was widely studied, leaving many forgotten samples in laboratories across the world. See Leslie Roberts, *The Exit Strategy*, 303 SCI. 1969, 1971 (2004).

²¹¹ See, e.g., Alibek, *supra* note 123, at S8 (“[T]he Rubicon has already been crossed and the process of creating novel genetically engineered orthopoxviruses is irrevocable. It is just a matter of time before this knowledge will result in the creation of super-killer poxviruses.”); Mintz & Warrick, *supra* note 208, at A6; All Health News, *WHO Smallpox Shift Ignites Debate*, available at <http://www.allhealthnews.net/news.html?view=16051> (last visited Sept. 8, 2005) (Dr. Ken Alibek, a bioweapons expert, stated that it is now possible to genetically engineer smallpox viruses that are infectious even in people who have received smallpox vaccinations.)

²¹² Both IPV and OPV are directed towards poliovirus serotypes 1, 2, and 3. See Plotkin et al., *supra* note 58, at 346; Sutter et al., *Live Attenuated Polio Vaccines*, *supra* note 35, at 378-79.

²¹³ See Geoffrey L. Smith & Grant McFadden, *Smallpox: anything to declare?*, 2 NATURE REVS. IMMUNOLOGY 521, 525 (2002).

vaccine.²¹⁴ Thus, there is no guarantee that existing vaccines are even capable of protecting against weaponized diseases.

B. *Recommendations for Future Use of Polio and Smallpox Vaccines*

Ironically, vaccines that have so effectively protected a generation from terrible illness and have led to the eradication of diseases could expose that same generation to future harm if the vaccines are no longer administered. IPV is safe²¹⁵ and has been associated with no serious adverse events to date,²¹⁶ aside from the Cutter incident.²¹⁷ therefore, continued use of IPV may be a reasonable means to prevent a bioterrorist attack. If continued use of IPV is indeed reasonable, then it is constitutional under *Jacobson*. However, several important changes to vaccination policy should be made regarding polio vaccination post-eradication, and regarding smallpox vaccination if ever again made mandatory.

1. Use of Polio Vaccine Post-Eradication

Once polio is certified for eradication, IPV and OPV should no longer fall under the provisions of NVICP.²¹⁸ At this point, polio and smallpox vaccination are not public health issues, they are national defense issues.²¹⁹

²¹⁴ While working with ectromelia virus (the cause of mousepox), a group of researchers in Australia introduced mouse genes to the virus in an attempt to increase antibody responses. The resulting recombinant virus was more virulent and infected mice that were genetically resistant to the wild-type virus. This implies that the smallpox virus could be similarly manipulated using human genes, creating a more virulent smallpox virus that is infectious even in immunized individuals. Although it is uncertain whether these mousepox results may appropriately be extrapolated to smallpox, this Australian study still warrants concern. See Smith & McFadden, *supra* note 213, at 525. See also Martin M. Weiss et al., *Rethinking Smallpox*, 39 CLINICAL INFECTIOUS DISEASES 1668, 1668 (2004) (“[A]dvances in genetic engineering may permit construction of [smallpox] strains able to evade the current vaccine . . . [C]onstrutions might be assembled using human smallpox virus (*Variola major*) or another pox virus (e.g., monkeypox virus) and human genes . . . [T]he possibility of a future bio-engineered attack using smallpox should not be arbitrarily rejected.”)

²¹⁵ Plotkin et al., *supra* note 58, at 356.

²¹⁶ CDC, *Poliomyelitis Prevention*, *supra* note 30, at 14.

²¹⁷ Plotkin et al., *supra* note 58, at 356.

²¹⁸ Conversely, smallpox should not be included in the NVICP table.

²¹⁹ See Bicknell & Bloem, *supra* note 127, at 2 (“[T]he decision regarding post-Iraq smallpox as a national security risk is for the intelligence community to assess, not for medical and public health personnel.”); George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 NEW ENG. J. MED. 1337 (2002). See generally Kellman, *supra* note 138.

NVICP was created to cover routine childhood immunizations,²²⁰ not to provide insurance against injuries resulting from homeland defense. Our national defense is assured by the Constitution,²²¹ and injuries to civilian citizens that arise from efforts to promote our national defense should not be capped by a statute designed to provide safe childhood immunizations for common diseases.

If polio immunization is continued as a routine childhood vaccination, only IPV should be used because it is safer than OPV.²²² The emergency stockpile of OPV should, however, be maintained to control future outbreaks.²²³ If a mandatory smallpox vaccination program is enacted, the scope of such a program should be designed with the input of physicians, vaccinologists, and public health experts. Existing CDC recommendations may serve as a starting point.²²⁴ Perhaps more importantly, safer smallpox vaccines must be developed to reduce the rate of adverse events associated with immunization.²²⁵ If a smallpox vaccine as safe and efficacious as IPV were available, the decision to vaccinate would be much easier. Because the possibility of a smallpox attack is unknown but is perceived by many to be very small, any administration of a smallpox vaccine must have very low risk of adverse events so that the benefit of the vaccine is assuredly greater than any potential harm. Safer smallpox vaccines are, therefore, required before instituting a mass vaccination program.

2. Assuring a Supply of Polio Vaccine

If IPV and OPV are removed from NVICP, manufacturers may withdraw from the market. In such an event, polio vaccine, and any other vaccine used expressly for national defense (i.e., smallpox or anthrax) should be manufactured by states or the Federal government. This is not a novel idea; Massachusetts manufactures its own diphtheria, tetanus, and pertussis

²²⁰ 42 U.S.C.A. 300aa-27(a)(1) (2004) (“In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines.”).

²²¹ U.S. CONST. pmb1.

²²² ACIP recommended the discontinuation of OPV use in 1999 in favor of IPV for safety reasons. See CDC, *Poliomyelitis Prevention*, supra note 30, at 17.

²²³ *Id.* at 14.

²²⁴ See generally CDC, *Pre-Event Vaccination*, supra note 122, at 1.

²²⁵ See Smith & McFadden, supra note 213, at 525-26 (The rates of complication associated with the current smallpox vaccine “are unacceptable for a modern-day vaccine.”); David L. Heymann, *Smallpox containment updated: considerations for the 21st century*, 8S2 INT’L J. OF INFECTIOUS DISEASES S15, S17 (2004) (WHO research agenda “includes research and development of new and safer smallpox vaccines.”)

vaccines under a license from FDA.²²⁶ Relying on private companies to provide sufficient quantities of vaccines to thwart a terrorist attack is also risky.²²⁷

If the government produces vaccines, a sufficient supply of vaccine can more easily be assured than by relying on private corporations. First, an agency whose sole purpose is to generate vaccines will not be sidetracked by rerouting production efforts into other products, unlike pharmaceutical companies who may need to temporarily halt vaccine production in favor of other more lucrative endeavors. Second, federal production of vaccines could actually be more efficient than private production. For instance, FDA oversees the safety, efficacy, and security of our nation's food supply and drugs.²²⁸ FDA is thus supremely qualified to operate a vaccine production facility in accordance with all manufacturing guidelines, as FDA creates these guidelines. If given the task of creating a sustainable supply of polio and smallpox vaccines, FDA would be unlikely to violate their own manufacturing guidelines because of their familiarity with the regulations. This in turn would reduce the number of noncompliant or tainted vaccine lots, helping to prevent the shortfalls associated with private production.²²⁹

CONCLUSION

Absent a terrorist threat, a mandatory smallpox vaccination requirement for access to public schools would clearly be an unconstitutional condition. Now that polio is on the cusp of eradication, mandatory vaccination

²²⁶ See University of Massachusetts Medical School, *Massachusetts Biological Laboratories*, <http://www.umassmed.edu/service/massbiolabs/> (last visited Jan. 13, 2005).

²²⁷ For instance, in 2001-2002, the United States had shortages of 8 of the 11 recommended childhood vaccines (diphtheria, pertussis, tetanus, measles, mumps, rubella, varicella, and pneumococcal conjugate vaccines). See Frank A. Sloan et al., *The Fragility of the U.S. Vaccine Supply*, 351 *NEW ENG. J. MED.* 2443 (2004). In 2004, production problems surrounding pneumococcal vaccine again caused a delay in vaccination when the manufacturer failed to produce enough of the vaccine to meet demand, prompting CDC to recommend that healthcare providers temporarily suspend administering the third and fourth dose of the four-dose regime for the vaccine. See Ctrs. For Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Updated Recommendations on the Use of Pneumococcal Conjugate Vaccine: Suspension of Recommendation for Third and Fourth Dose*, 53 *MORBIDITY & MORTALITY WKLY. REP.* 177 (2004). More recently, the United States suffered a shortage of influenza vaccine, also caused by production problems, when nearly half of the U.S. supply of this vaccine was lost due to compromised sterility of the product. See Andrew Pollack, *U.S. Will Miss Half Its Supply of Flu Vaccine*, *N.Y. TIMES*, Oct. 6, 2004, at A1. Such a delay or shortage would obviously be a major problem in the event of a terrorist attack.

²²⁸ See U.S. Food & Drug Admin., *FDA's Mission Statement*, available at <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Jan. 14, 2005).

²²⁹ See *supra* note 227.

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for this disease is also an unconstitutional condition, absent a terrorist threat. If state governments wish to continue mandatory vaccination for polio, or to renew vaccination programs for smallpox, these vaccines should not fall within the no-fault exemption of NVICP. To assure a sufficient supply, state governments should consider manufacturing these vaccines for their use or turn to the federal government to provide a national supply of safe and reliable products.

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