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THE VACCINE WARS: WHAT CAN BE LEARNED FROM CALIFORNIA'S EXPERIENCES WITH MANDATORY IMMUNISATION OF SCHOOL CHILDREN?¹

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Abstract

The almost universal administration of childhood immunisations has been associated with logarithmic drops in the incidence of a number of diseases in the United States and worldwide. In the United States, mandatory school immunisation laws have in particular been instrumental in achieving the high levels of coverage needed to sustain herd immunity. However, concerns about vaccine safety led to the passing of the National Childhood Vaccine Injury Act of 1986, which uses a no-fault system compensation system for people found to be injured by certain vaccines. The measles vaccine is highly effective, and outbreaks of measles are usually the consequence of failure to vaccinate. A high-profile outbreak of measles at a southern California amusement park in 2014 led the state of California to further restrict the ability of children to attend school if they are not immunized because of their family's beliefs. Immunisation requirements are but one of many legal mandates designed for public health protection, from mandatory fluoridation of drinking water to quarantine and isolation for communicable diseases. We conclude that school immunisation requirements help governments fulfil their duty to protect and promote public health.

Keywords: *immunisations, public health law, California, pertussis, measles*

1. INTRODUCTION²

On a global scale, the incidence and associated mortality of infectious diseases has fallen steadily since the mid-1950s (Hinman, 1989). This decline has been particularly noted for vaccine-preventable diseases, including diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps and rubella (CDC, 1999). In more recent times, immunisation helped

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eradicate smallpox by 1978 (Fenner, 1982), eliminated endemic polio, rubella and measles in the Americas (PAHO, 2015, 2016), and virtually eliminated invasive *Haemophilus influenzae* type b infections in high-income countries (Peltola, 2000).

These declines in mortality are especially evident in children. For instance, in a particularly careful analysis undertaken in the Netherlands, the years of life lost before 20 years of age fell steadily from the cohort of children born in 1903 to the cohort born in 1992 (van Wijhe et al., 2016). Mortality declined most precipitously for diphtheria and pertussis, and the authors have calculated that there were 3,000 fewer deaths and 38,000 fewer years of life lost before age 20 from diphtheria, and 6,000 fewer deaths and 103,000 fewer years of life lost before age 20 from pertussis after the introduction of mass vaccination programmes for these agents in 1953 and 1954 respectively (van Wijhe et al., 2016). Equally impressive was the rapid decline in *Haemophilus influenzae* type b. In the United States of America, for example, the incidence of invasive disease declined from a high of 25 cases per 100,000 children under 5 years of age in 1984 to almost 0 in 1997 (Adams et al., 1993; CDC, 1998). This was due to the introduction of a single-dose polysaccharide vaccine in 1986 and then a multi-dose conjugate vaccine series in 1990. It has been estimated that mass vaccination against *Haemophilus influenzae* type b has saved 13,700 lives in the United States from 1994 to 2013 (CDC, 2014). Despite the clear public health success of mass childhood immunisations, such programmes are not without their critics. In this paper we review the United States experience with mandatory childhood immunisations and one state's (California) experience with these programmes.

2. IMMUNISATION REQUIREMENTS FOR SCHOOL ENTRY, UNITED STATES

In the United States, public health law is primarily the province of state governments. Each state enacts its own set of public health laws, which can differ from state to state. Federal public health law is largely restricted to issues of communicable disease control at national borders and regulation of interstate commerce, for instance, of drugs and diagnostic devices (Gostin and Wiley, 2016). The federal government provides funding and technical assistance to states through agencies such as the Centers for Disease Control and Prevention in order to assist them in promoting public health in general and to control communicable diseases of public health significance in particular.

The responsibility of the states for public health derives from their duty to protect their citizens and have their origin in their police powers (Gostin and Wiley, 2016). For communicable disease control, the states have the power to limit individual liberty in order to protect public health through interventions such as quarantine and isolation. Immunisation requirements are an extension of these duties and powers. But, as with many laws, there is a balance between protecting public health while preserving individual liberties and commerce to the greatest extent possible. Overriding all these considerations is the medical tenet of doing no harm (Gostin and Gostin, 2009).

There is a long history of requiring citizens to be immunised in the United States (Cole, and Swendiman, 2014). The first school vaccination requirements were enacted in 1850 in Massachusetts to prevent smallpox. As early as 1905, the United States Supreme Court in *Jacobsen versus Massachusetts* rejected the argument that an individual could refuse to be vaccinated for smallpox because he knew best how to care for his own body (Parmet et al., 2005; Duffy, 1978). This landmark decision and others that followed allowed states to enact laws and regulations that required children to be immunised for certain communicable disease prior to entering school, and by 1980, all states had such requirements (Hinman et al., 2002). At the same time, almost all states allowed exemptions for medical contraindications or for philosophical or religious reasons. Figure 1 shows which states allowed for religious exemptions and religious or philosophical exemptions in 2015 (NCSL, 2016). Only two states at that time, Mississippi and West Virginia, did not allow these exemptions.

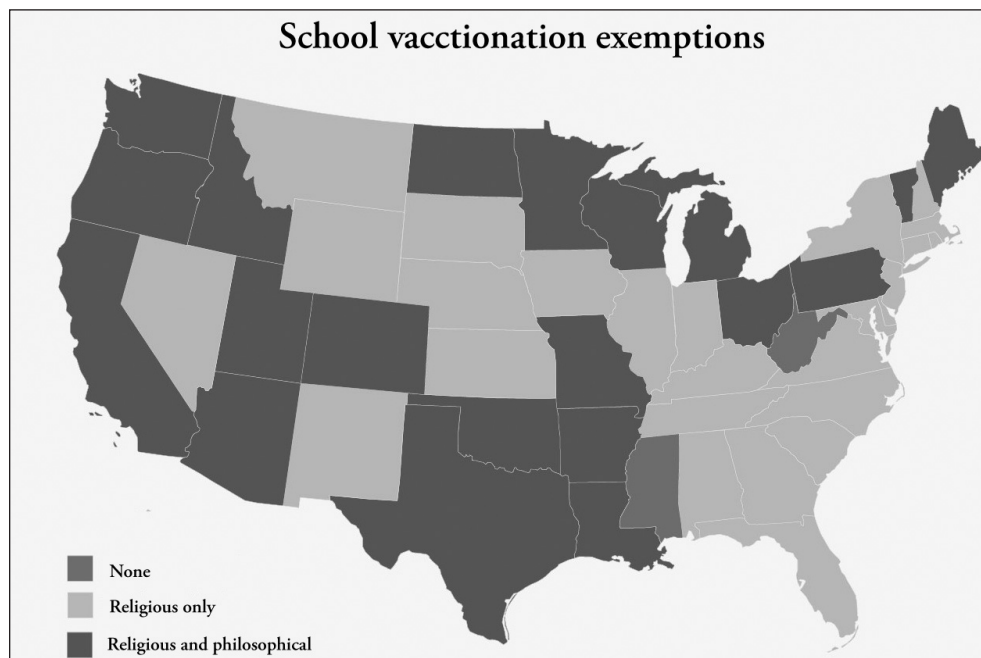


Figure 1. *Religious and philosophical exemptions to school vaccination laws by state, United States of America, 2015 (Hinman et al., 2002).*

The United States has long recognised that there is a low background rate of severe adverse events following childhood immunisation that can lead to permanent harm. Along with individual rights, issues of avoiding potential harm are at the heart of the

anti-vaccination movement (College of Physicians of Philadelphia, 2017). To remedy injuries that might have resulted from mandatory immunisation, the United States enacted the National Vaccine Compensation Act in 1986 (Smith, 1988). The Act created a no-fault alternative system to the traditional tort system for immunisation-associated injuries. As a result, it was anticipated that the Act would help retain vaccine manufacturers on the market, assure an adequate supply of vaccines, and stabilise vaccine prices. Compensation is funded by a \$0.75 excise tax on each of the covered vaccines (HRSA, 2017). The claims process has five steps (see Box 1).

When pre-specified conditions, such as anaphylaxis, occur within defined time periods after immunisation, it is presumed that the vaccine was the cause unless proven otherwise, and the affected individual is eligible for compensation. Persons with injuries that are not pre-specified are still eligible for compensation if they can prove that immunisation was the cause. There were 3,521 claims filed from 2006 to 2014, against a background of 2.5 billion doses administered (one claim for every 710,000 vaccines administered). Of these 3,521 claims, 2,248 (64%) received compensation. Since the programme began in 1988, the total amount awarded has been \$3.4 billion for 4,804 compensated claims (\$70,000 per claim).

Immunisation against up to nine pathogens is currently required for entering California schools, whether they be public or private, or to pre-schools and child care centres. Immunisations required for kindergarten include poliomyelitis (4 doses), diphtheria and tetanus toxoids and pertussis vaccine (5 doses, as DTP, DTaP or DT), hepatitis B (3 doses), measles, rubella and mumps (2 doses of measles-containing vaccine), and varicella (1 dose) (Smith, 1988). DTP can be administered as whole cell pertussis vaccine (P), which is no longer available in the United States, or acellular pertussis vaccine (aP). Children who have had adverse events after DTP or DTaP may complete their requirements with diphtheria and tetanus toxoids (DT).

Additionally, children entering or advancing into seventh grade are required to have an additional dose of reduced diphtheria toxoid, tetanus toxoids and acellular pertussis vaccine (Dtap). Prior to 2016, California law allowed for two types of exemptions to these required immunisations: those based on medical reasons, such as immunosuppression, which could be either permanent or temporary, and those due to personal beliefs, whether religious or otherwise. Over the last 15 years, the proportion of children entering kindergarten in California who have had all their required immunisations has fallen from almost 93% to less than 91%. This decline was much more pronounced for children entering private schools, where coverage fell from 90% to 86% (Figure 2). In the autumn of 2015 of the 551,123 children entering kindergarten in California, 511,708 (92.9%) were reported as having received all their required immunisations, 24,424 (4.4%) had been admitted conditionally, meaning that they were still completing their requirements after past delays or had temporary medical exemptions, and 974 (0.2%) were overdue for their final immunisation (HRSA, 2017). An additional 931 (0.2%) children had permanent medical exemptions, and 13,086 (2.4%) claimed personal belief exemptions.

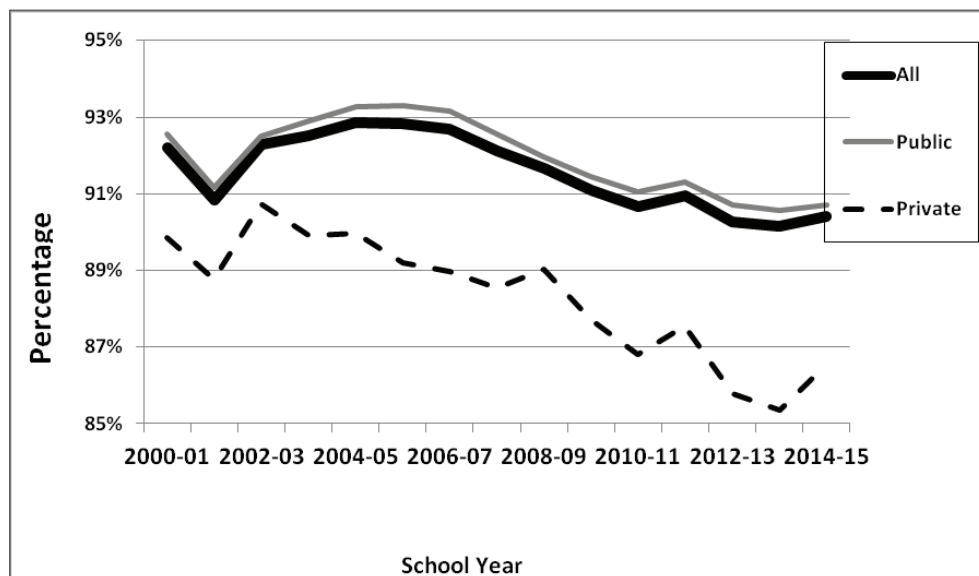


Figure 2. *Percentage of California kindergarten enterers with all required immunisations by school type, 2000-2001 to 2014-2015.*

3. THE PROBLEM WITH MEASLES

Measles is possibly the most infectious of childhood diseases. Spread in respiratory secretions, the measles virus can cause severe multiorgan system disease (Holzmann et al., 2016). Young children who are exposed after the transplacental maternal antibody wanes are at particularly high risk of life-threatening sequelae, such as pneumonia and diarrhoea. Thus, infants and young children need to be immunised as soon as possible after maternal antibodies have disappeared; in the United States, the recommended age for measles immunisation is typically between 12 and 15 months of age (CDC, 2013). The extreme contagiousness of measles is reflected in an estimated 92-94% threshold herd immunity level necessary to interrupt transmission (Fine and Mulholland, 2008). Failures either to achieve or sustain such levels of immunity are the main challenges with measles. If parents wait to immunise their children against measles until entering school at 5 years of age, the ensuing pool of non-immune children can sustain an epidemic transmission. This is what happened in California, and indeed throughout the Western Hemisphere, from 1988 to 1990 (Dales et al, 1993). Once widespread transmission starts, measles spreads not only to unvaccinated people who had not been exposed to endemic measles in the years since the measles vaccine was introduced, but also to those whose immunisations have failed. The measles vaccine is ineffective in about 5% of children immunised in the absence of a maternal antibody. If revaccinated, 95% of this 5% will become protected. To close this gap in immunity, in 1989 the US Advisory

Committee on Immunization Practices recommended a second dose of measles vaccine (usually given with the mumps and rubella vaccine) for children right before entering school (National Vaccine Advisory Committee, 1991).

Measles outbreaks can also occur in populations whose philosophical or religious beliefs preclude the attainment of herd immunity. In the wake of well-publicised allegations of autism occurring after receiving the MMR vaccine, which was sparked by a case series published in 1998 that was eventually retracted, MMR immunisation rates for young children in the United Kingdom fell well below the herd immunity threshold (ECDC, 2008). Even after concerns about the safety of MMR had faded and immunisation rates in early childhood had reversed, many older children and adolescents never received remedial immunisation (Abertawe Bro Morgannwg University Health Board et al. 2013). In 2013 an outbreak in Wales resulted in more than 1,200 cases of measles, with 88 people hospitalised and 1 fatality (Abertawe Bro Morgannwg University Health Board et al. 2013). Most of those afflicted were younger than 15 years of age, and many were unvaccinated, the deferred casualties of the MMR safety scare. In 2014 two outbreaks of approximately 400 cases each resulted when travellers to Europe and Asia imported measles to religious communities in North America with low immunisation rates (Naus, et al. 2015; Glover, C. E., 2015).

Soon thereafter, an outbreak of measles following exposure at a southern California amusement park in December 2014 (CDC, 2015b) led to 125 cases in seven states, Canada and Mexico. Of the 110 cases that occurred in California, at least 60 (55%) were unvaccinated; 13 of these were too young to have received the measles vaccine at the recommended age, and at least 37 individuals had not been immunised against measles because of their families' personal beliefs.

This highly-publicised amusement park outbreak led to the introduction in 2015 of California Senate Bill (SB) 277, which proposed to eliminate personal belief exemptions for new entrants into public and private schools and child care centres. Children who had received personal belief exemptions before 2016 could remain in school under their exemptions until they entered kindergarten (for the case of children in pre-school or child care centres) or 7th grade (the grade children enter at 12 years old, for the case of children already in elementary school). Children receiving home-based instruction and those enrolled in independent study programmes outside of the classroom would no longer be subject to school immunisation requirements (California Legislative Information, 1995). Advocates for the legislation included parents of a child with leukaemia concerned about potential exposures to vaccine-preventable diseases from unimmunised peers. The proponents noted that, despite the recent implementation of more stringent requirements for personal belief exemptions, in the autumn of 2014 only 92.6% of children entering kindergarten in California were reported as having had two MMRs (California Department of Public Health, 2016b), and 1199 (17%) kindergartens with 10 or more children reported more than 5% of pupils having personal belief exemptions to one or more required immunisations (California Department of Public Health, 2016a).

SB 277 passed through both the California Assembly and the State Senate and was signed into law by Governor Jerry Brown on June 30, 2015. As a result, California became the third state in the United States to disallow personal belief exemptions to entering school. In his accompanying message, Governor Brown wrote:

“The science is clear that vaccines dramatically protect children against a number of infectious and dangerous diseases. While it’s true that no medical intervention is without risk, the evidence shows that immunization powerfully benefits and protects the community.” (Brown, 2015).

Thus, in California at least, mandatory school immunisation requirements codified in laws and regulations have been established as a prudent measure designed to protect both public health as well as individuals from infectious diseases.

4. PARALLELS TO OTHER COMMUNICABLE DISEASE CONTROL PROGRAMMES

In addition to childhood immunisation programmes, public health law also allows for a number of other proscriptive activities to protect public health and control the spread of both communicable and at least a few non-communicable diseases. They generally fall into three groups – activities that support acquisition of data for public health and disease control efforts, activities that involve mass administration of drugs, and activities that directly limit individual liberties in order to protect public health.

Disease reporting and surveillance are long-standing public health activities. They are needed to assist public health agencies in identifying individual cases of disease (for instance, individual cases of measles) as well as to understand the epidemiology of a disease and the on-going patterns of disease transmission (Declich and Carter, 1994). Case reporting for individual cases of HIV was particularly controversial when there were few therapeutic options and prevention was limited to counselling and condom provision (Bayer and Fairchild, 2002). Interestingly, this rapidly changed with the widespread availability of antiretroviral drugs (UNAIDS, 2014), changes in antiretroviral treatment guidelines to recommend treatment for everyone with HIV (WHO, 2015b), and the discovery that antiretroviral therapy can virtually eliminate further sexual transmission of HIV (Rutherford and Anglemyer, 2016). More recently data from case reporting has become the cornerstone of monitoring and evaluating national and worldwide progress to elimination of HIV (WHO, 2015a).

A second group of mandatory public health activities is mass screening, treatment or preventive supplementation, the latter including the addition of fluoride to drinking water (Iheozor-Ejiofor et al., 2015), iodide to salt or vitamins to cereal grains (Raitiainen et al., 2016); a prominent example is the decision to supplement cereal grains consumed by pregnant women with folic acid to prevent neural tube defects in fetuses (Ray et al., 2002). Mass drug administration may also be done at the individual level, such as administration of topical antibiotics to all newborns to presumptively treat gonococcal ophthalmia and parenteral vitamin K to prevent neonatal haemorrhage (Zi-

pursky, 1999). In tropical countries where malaria is endemic all pregnant women are treated presumptively in the third trimester with antimalarial drugs to prevent the congenital transmission of malaria (WHO and Global Malaria Programme, 2012). Mass screening programmes focus on identifying newborns with certain metabolic diseases that can be ameliorated if treated very early in life, such as congenital hypothyroidism and phenylketonuria (Green et al., 2006). In all these cases the state mandated diagnostics, preventive measures and therapeutics, either directly through law or by defining the standard of care, to protect unborn and newborn children.

Public health laws permitting isolation and quarantine control the spread of communicable diseases at the cost of restricting individual liberties. Isolation refers to limiting the movement of a person with a communicable disease during the infectious period of that disease in order to prevent spreading of the disease. Quarantine, on the other hand, refers to limiting the movement of a person who has been exposed to (and may be infected with) a communicable disease during the potential incubation period of the disease. Quarantine and isolation were widely and effectively used to limit transmission and protect public health during the severe acute respiratory disease (SARS) outbreak in China in 2003 (Bondy et al., 2009) and in the recent Ebola virus outbreak in West Africa (CDC, 2015a).

5. CONCLUSIONS

In the United States of America there is a substantial corpus of state and federal law designed to protect public health from the spread of communicable diseases. Here we have reviewed mandatory school immunisation laws in California and how they have changed over time. They are, however, but one example of how the duties of states to protect public health are translated into interventions.

In order to limit the transmission of vaccine-preventable diseases, mandatory school immunisation laws must support the attainment and maintenance of herd immunity. Society has a vested interest in preventing the transmission of these diseases and the morbidity and mortality they cause. While waning immunity and vaccine failure do occur, epidemic disease transmission far too often is the result of failure to vaccinate rather than vaccine failure. In an ideal world, all infants and young children would be fully and promptly immunised without intervention from the state. Until that day dawns, school immunisation laws have proven to be an effective way to support vaccine coverage goals and to protect public health.

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1. An individual files a petition with the U.S. Court of Federal Claims.
2. The U.S. Department of Health and Human Services' (DHHS) medical staff reviews the petition, determines if it meets the medical criteria for compensation and makes a preliminary recommendation.
3. The U.S. Department of Justice develops a report that includes the medical recommendation and legal analysis and submits it to the Court.
4. The report is presented to a court-appointed special master, who decides whether the petitioner should be compensated, often after holding a hearing in which both parties can present evidence. If compensation is awarded, the special master determines the amount and type of compensation.
5. The Court orders DHHS to award compensation. Even if the petition is dismissed, if certain requirements are met, the Court may order DHHS to pay attorneys' fees and costs.

Note: The special master's decision may be appealed and petitioners who reject the decision of the court may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine.

Box 1. *How the National Vaccine Injury Compensation program works (College of Physicians of Philadelphia, 2017).*

RATOVİ CJEPİVA: ŠTO MOŽEMO NAUČITI IZ KALIFORNIJSKOG ISKUSTVA S OBVEZNIIM CIJEPLJENJEM ŠKOLSKE DJECE?

George W. Rutherford i Robert Schechter

Sažetak

Gotovo univerzalna imunizacija djece povezana je s logaritamskim opadanjem broja zaraza kako u Sjedinjenim Državama tako i svijetu. U Sjedinjenim Državama, zakon o obveznom cijepljenju školske djece pokazao se posebno korisnim za postizanje visokog stupnja zaštite potrebne za održavanje imunosti zajednice. Međutim, zabrinutosti oko sigurnosti cjepiva dovele su do donošenja National Childhood Vaccine Injury Act (Nacionalni zakon o štetnosti dječjeg cjepiva) iz 1986., prema kojem se kroz „no-fault sustav“ (bez obzira tko je kriv) kompenziraju oštećeni određenim cjepivima. Cjepivo protiv ospica iznimno je učinkovito, a pojave ospica najčešće su povezane s neprimanjem cjepiva. Zbog poznatog slučaja pojave ospica u kalifornijskom zabavnom parku 2014., savezna država Kalifornija dodatno je ograničila mogućnost pohađanja škole djece koja nisu cijepljena zbog obiteljskih uvjerenja. Obvezno cijepljenje predstavlja samo jednu od odredbi kojima je cilj zaštita javnog zdravlja, a ,edu kojima su i obvezna fluoridacija pitke vode i karantena i izolacija zbog prenosivih bolesti. Zaključujemo da obvezno cijepljenje školske djece pomaže vladama u ispunjenju njihove dužnosti u zaštiti i unaprjeđenju javnog zdravstva.

Ključne riječi: cijepljenje, zakon o javnom zdravstvu, Kalifornija, hripavac, ospice

IMPFKÄMPFE: WAS KÖNNEN WIR AUS DER KALIFORNISCHEN ERFAHRUNG MIT DER PFLICHTIMPFUNG DER SCHULKINDER LERNEN?

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Zusammenfassung

Eine fast universelle Immunisierung der Kinder ist, sowie in den USA als auch in der übrigen Welt, mit einer logarithmischen Abnahme der Ansteckungsfälle verbunden. In den USA hat sich das Gesetz über die Pflichtimpfung von Schulkindern als besonders nützlich zum Erreichen einer hohen Stufe des für Erhalten der Immunität der Gemeinschaft nötigen Schutzes erwiesen. Allerdings haben die Bedenken über die Impfsicherheit zum Erlassen des Nationalen Kindheits-Impfstoff-Verletzungsgesetz aus dem Jahr 1986 (National Childhood Vaccine Injury Act) geführt, wonach durch ein „No-Fault-System“ (ungeachtet dessen, wer die Schuld trägt) die durch bestimmte Impfstoffe Betroffenen entschädigt werden. Der Masernimpfstoff ist außerordentlich effizient und die Masernfälle sind meistens mit der Nichtimpfung verbunden. Wegen des bekannten Falls des Masernausbruchs im kalifornischen Vergnügungspark 2014 hat der Bundesstaat Kalifornien zusätzlich den Schulbesuch von Kindern beschränkt, die aus Familienüberzeugung nicht geimpft wurden. Die Pflichtimpfung ist nur eine von Bestimmungen, deren Ziel der Schutz der öffentlichen Gesundheit ist, dazu gehören noch die obligatorische Trinkwasserfluoridierung, Quarantäne und und Isolation wegen übertragbaren Krankheiten. Wir kommen zum Schluß, dass die Pflichtimpfung von Schulkindern den Regierungen hilft, ihre Pflichten im Rahmen des Schutzes und der Förderung der öffentlichen Gesundheit zu erfüllen.

Schlüsselwörter: Impfung, Gesetz über den öffentlichen Gesundheitsdienst, Kalifornien, Keuchbusten, Masern