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Vaccines: when should we legislate?

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**Abstract**

Vaccines: when should we legislate?
By Jennifer A. Beeler

Vaccination has proven to be an effective method of controlling and preventing the spread of many infectious diseases. Due to routine immunization in the United States, mortality rates due to diphtheria, pertussis, tetanus, and mumps have been reduced by 99%, and compulsory vaccination laws have resulted in near record high vaccination coverage among school-age children. Compulsory vaccination laws have been in effect since the 19th century, and have been generally well accepted. However, vaccine mandates have also been met with ardent opposition from various groups, including certain religious factions. Some religious groups believe that mandatory vaccination laws violate their religious freedom, while others argue that compulsory vaccination infringes upon their personal autonomy. Furthermore, some have expressed concern over the possible, but unlikely, risks associated with vaccination, and the number of vaccines that children receive. All states, with the exception of West Virginia and Mississippi, permit religious exemptions, allowing followers of certain religious beliefs to opt-out of vaccination laws. Additionally, 20 states allow for philosophical or personal belief exemptions. In order to maintain high vaccination coverage and prevent infectious disease outbreaks, state legislators must propose dynamic legislation restricting, but not eliminating nonmedical (i.e. religious and philosophical) exemptions. Ultimately, by broadening administrative requirements for nonmedical exemptions, policy makers will tip the "balance of convenience" in favor of vaccination, making vaccination the default option.

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**Abstract**

Vaccination has proven to be an effective method of controlling and preventing the spread of many infectious diseases. Due to routine immunization in the United States, mortality rates due to diphtheria, pertussis, tetanus, and mumps have been reduced by 99%, and compulsory vaccination laws have resulted in near record high vaccination coverage among school-age children. Compulsory vaccination laws have been in effect since the 19th century, and have been generally well accepted. However, vaccine mandates have also been met with ardent opposition from various groups, including certain religious factions. Some religious groups believe that mandatory vaccination laws violate their religious freedom, while others argue that compulsory vaccination infringes upon their personal autonomy. Furthermore, some have expressed concern over the possible, but unlikely, risks associated with vaccination, and the number of vaccines that children receive. All states, with the exception of West Virginia and Mississippi, permit religious exemptions, allowing followers of certain religious beliefs to opt-out of vaccination laws. Additionally, 20 states allow for philosophical or personal belief exemptions. In order to maintain high vaccination coverage and prevent infectious disease outbreaks, state legislators must propose dynamic legislation restricting, but not eliminating nonmedical (i.e. religious and philosophical) exemptions. Ultimately, by broadening administrative requirements for nonmedical exemptions, policy makers will tip the "balance of convenience" in favor of vaccination, making vaccination the default option.

## Introduction

Vaccination has proven to be an effective method of controlling and preventing the spread of infectious disease for nearly 200 years. Vaccines played a critical role in the global eradication of smallpox, considered to be one of the greatest immunization and collaborative public health successes to date [1, 2]. In addition to the global eradication of smallpox, vaccines have led to the elimination of measles in the Americas, and the near elimination of wild-type polio worldwide. Prior to the 20th century, approximately half of all children born in the United States died as a result of infectious diseases. Since the introduction of routine immunizations in the United States, mortality rates due to diphtheria, pertussis, tetanus, and mumps have decreased by 99% [3, 4], and the use of *Haemophilus influenzae* type B (Hib) conjugate vaccines has nearly eliminated Hib invasive disease in infants and children [5].

## History of Compulsory Vaccination Laws

Controlling infectious disease by means of compulsory vaccination legislation has been in effect since vaccines were first introduced in the 19th century [5]. Numerous countries have implemented compulsory vaccination laws, including the United Kingdom, the United States, as well as several nations in Eastern Europe.

In the mid-19th century, the Vaccination Act of 1853 required residents in England and Wales to be vaccinated against smallpox in order to control, and ultimately prevent outbreaks of the deadly disease [6, 7]. While the majority of citizens willingly received the vaccine, some groups adamantly opposed the Vaccination Act, seeing it as intrusive, and an abuse of government authority. In 1889, the Royal Commission on Vaccination began its investigation into the

effectiveness of vaccination as a means to control smallpox, and began to evaluate existing compulsory immunization laws, and what could be done to improve vaccine safety. The Commission recognized the importance of vaccination as a major contributor to the decrease in smallpox incidence, but recommended the inclusion of a conscientious exemption clause, allowing individuals who were "honestly opposed" to vaccination to be exempt from immunization mandates. Ultimately, the inclusion of conscientious exemptions *increased* the number of vaccinated children [7-9].

In 1905, Henning Jacobson of Cambridge, Massachusetts, questioned the constitutionality compulsory vaccination laws in the United States. Nearly a century earlier, Massachusetts introduced compulsory vaccination to control the spread of smallpox in the general population[7]. Jacobson refused to be vaccinated, arguing that the law violated his personal autonomy [7, 10]. In his appeal to the United States Supreme Court, Jacobson stated that:

> "A compulsory vaccination law is unreasonable, arbitrary and oppressive, and therefore, hostile to the inherent right of every freeman to care for his own body and health in such ways as to him seems best; and that the execution of such a law against one who objects to vaccination, for whatever reason, is nothing short of an assault upon his person" [11].

In response to his appeal, the Supreme Court upheld the right of the state to require vaccination, stating that it was a justifiable use of their powers [11]. These powers allow the state to enact and impose laws protecting the health, safety, and welfare of the public[12]. The Court ruled that:

> "The liberty secured by the constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all

circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good" [11].

Since this landmark Court decision, the U.S. Supreme Court has consistently ruled in favor of state vaccination laws [13], despite fervent opposition from various groups.

In the 1960s and 1970s, difficulties in controlling measles outbreaks prompted the introduction of modern school immunization laws in the United States [14, 15]. In 1969, 17 states had enacted laws requiring children to be vaccinated against measles prior to entering school, and only 12 states required vaccination against all six diseases for which routine immunization was available. During the 1970s, these laws were strengthened, and efforts were taken to improve enforcement. By the 1980s, all states had implemented legislation requiring immunization prior to school entry, and establishing vaccination as the default option [14-17].

**School Entry Vaccination Requirements**

All U.S. states have school entry vaccination requirements [18]. These laws serve to make immunization a priority, helping to ensure that nearly all children are immunized prior to school entry regardless of socioeconomic status, race, or ethnicity. Additionally, these laws lay the foundation for a reliable "system of immunization" that continues to function regardless of the current political climate, media coverage, and state budgets. More importantly, this "system of immunization" continues to work when disease incidence is low, and when interest and fear of infectious diseases are minimal [15]. Furthermore, school-entry requirements are effective as they are generally accepted by communities, endorsed by local physicians, and help secure resources for immunization efforts [5].

While these laws have been effective in increasing vaccine coverage and have decreased the occurrence of disease outbreaks in schools, school entry vaccination requirements have faced ardent opposition from diverse groups [19]. Various religious groups including Christian Scientists, and some Amish and Dutch Reform churches oppose immunization, believing that compulsory immunization laws undercut their religious freedom. Alternatively, some groups are fervently against mandates, and believe that not being given a choice in whether or not their child should be vaccinated violates their personal liberty [3]. Additionally, a growing number of parents have expressed concerns regarding the safety of vaccines, as well as the number of vaccines that children receive based on national recommendations determined by the Advisory Committee on Immunization Practices (ACIP) or the American Academy of Pediatrics. One study found that 69% of parents who did not vaccinate their children did so due to concerns that vaccines may cause harm, and that parents of unvaccinated and under-vaccinated children are more likely to believe that children receive too many vaccines [14].

**School Entry Exemption Policies**

Medical exemptions are granted to individuals who are immunocompromised, have a documented allergy to a vaccine component, or have been diagnosed with a moderate or severe illness [13]. In order to qualify for a medical exemption, parents typically must provide a letter from a physician documenting their child's medical condition [13]. All states, except Mississippi and West Virginia, allow for religious exemptions [17]. Religious exemptions are intended for followers of recognized religions whose beliefs prohibit modern medical practices or technologies [20]. Several states, including California and Pennsylvania, have expanded non-medical exemptions to include personal beliefs and strong moral convictions, consistent with

philosophical exemptions in other states [21]. Additionally, 20 states permit exemptions on philosophical grounds. Notably, only two states, Mississippi and West Virginia, do not permit non-medical exemptions [18].

For the 2013-2014 school year, the Centers for Disease Control and Prevention determined that the median overall exemption rate for kindergarteners in the United States was 1.8% for participating states. However, exemption rates varied considerably among states, with the lowest exemption rates being found in Mississippi (<0.1%) and the highest found in Oregon (7.1%). When reported separately, the median nonmedical exemption rate was 1.7% in states permitting religious or philosophical exemptions. However, this rate also varied significantly between states, with the lowest exemption rates found in Virginia and the District of Columbia (0.4%) and the highest found in Oregon (7.0%) [22].

**Claiming Nonmedical Exemptions**

The processes by which nonmedical exemptions are granted vary by state. Several states, such as Vermont, merely require a parent or guardian to complete and sign an exemption form, which is freely available online, and submit the form to their child's school [23]. In contrast, parents in Oregon can speak with a health care provider to acquire a Vaccine Education Certificate, and must then submit the completed certificate to their child's school or daycare center. Alternatively, the parent or guardian may choose to complete an online educational module, and print out a completion certificate to submit to their child's school or child care center [24]. Other states, such as Texas and Minnesota require notarization, adding another layer of complexity to

claiming an exemption [25, 26]. In fact, in numerous states, claiming a nonmedical exemption requires less effort than meeting immunization requirements set forth by the state [7].

Studies have shown that there is an inverse relationship between complexity of exemption procedures and the proportion of children claiming exemptions [20, 27]. States that have implemented more difficult and complex exemption procedures generally had lower exemption rates than states that had simpler and less labor-intensive processes [20]. States with simple exemption policies had nonmedical exemption rates that were 2.3 times higher than states with complex exemption procedures. Moreover, increases in exemption rates were only observed in states with philosophical exemptions and relatively simple exemption procedures [27].

**Nonmedical Exemptions: Necessary or Dangerous?**

Nonmedical exemptions have an inimitable place in U.S. vaccination legislation. U.S. citizens are granted the right to religious freedom [12]. However, the right to religious freedom is not definite under all circumstances. The Arkansas Supreme Court ruled that the State has the authority to reject religious exemptions, and that doing so does not violate the constitutional right to religious freedom as the actions of the State are in best interest of the public's health and safety [28]. Therefore, states are not required to allow religious exemptions. For example, Mississippi Supreme Court ruled that religious exemptions "violate equal protection of the laws under the Fourteenth Amendment," as exempt children can expose vaccinated children to potentially harmful infectious diseases [29, 30]. However, religious exemptions enable parents who are sincerely opposed to vaccination on moral and ethical grounds, to claim exemptions for

their children [29]. Additionally, religious exemptions allow for a high degree of personal autonomy, an ideal and freedom cherished in a democratic society.

Similarly, philosophical exemptions grant personal freedom, allowing individuals to decide whether or not vaccinations are right for themselves and their families. Moreover, they allow those with strong personal views against vaccination to opt out of vaccination mandates. Proponents for philosophical exemptions argue that it is the right of the individual, rather than the state, to decide what happens to one's own body. However, there is no legal basis for which philosophical exemptions should be permitted. Choosing not to vaccinate has broad implications, not only for oneself or one's child, but also for society. As increasing numbers of parents are claiming nonmedical exemptions for their children due to political or sociological beliefs, or because of safety concerns, the potential for disease outbreaks grows.

Studies have found that children who have received exemptions are significantly more likely to contract measles and pertussis. In fact, exempt children were 22-35 times more likely to contract measles than vaccinated children [13, 31], and nearly 6 times more likely to become infected with pertussis [31]. These studies demonstrate that there is an elevated risk of illness in unvaccinated individuals, but also suggest that unvaccinated children can transmit infection to vaccinated children during disease outbreaks [31]. While the vast majority of children meet school-entry vaccination requirements, the introduction of nonmedical exemptions has contributed to increases in exemption rates, and an overall increase in the likelihood of a child obtaining an exemption [32, 33]. Moreover, exemption rates have continued to increase, and the rate of increase has accelerated [27].

Given the importance of constitutional rights and personal autonomy in a democratic society, policymakers must carefully weigh the rights of individuals who seek exemptions against the risk of disease that endangers the public [13]. Policy makers must consider two directives. First, they must consider the health of the child who is to be vaccinated, including the risks associated with both vaccination and exemption. Second, they must consider the health of society as a whole, as widespread vaccine acceptance is necessary in order to protect communities from disease and maintain herd immunity [17]. Legislators must employ a dynamic approach to immunization policy decisions with beneficence, justice, nonmaleficence, and utilitarianism, and seek a balance between individual autonomy and promoting public health [17, 34]. Proposed legislation should aim to restrict, not eliminate nonmedical exemptions, through the incorporation of rational administrative requirements, and financial penalties and incentives.

**Recent Vaccine-Related Legislation**

State legislative bodies are frequently reviewing immunization policies [17]. Between 2009 and 2012, 18 U.S. states introduced, or attempted to enact, new legislation to modify exemptions to school immunization requirements. Of the 36 bills that were voted upon by state legislators, only 5 sought to restrict exemptions, while 31 bills, if passed, would have expanded exemptions. No bills that would have expanded exemptions were passed. However, between 2009 and 2012, Washington, California, and Vermont legislators passed bills to restrict exemptions in their respective states [35]. This year, legislators in Washington, Oregon, and California have filed new legislation to eliminate philosophical exemptions [17, 36-38]. Yet, attempts to enact legislation to further restrict nonmedical exemptions have failed both in Oregon and Washington,

due to inadequate support from lawmakers and fervent opposition from some groups [36]. Similarly, North Carolina legislators have introduced a measure that, if passed, would end religious exemptions in their state, effectively eliminating nonmedical exemptions all together [39].

**Rational Administrative Requirements**

Broadening administrative requirements for vaccination exemptions is one method legislators could pursue as a means to balance the rights of the individual and the greater public good [14]. Rational administrative requirements serve to remind parents of the importance of vaccination, and make vaccination more convenient than claiming a nonmedical exemption. These requirements should not only make the exemption process more complex, but should also educate parents about vaccines and vaccine safety, and how vaccines protect their child as well as those around them.

Exemption processes could also be made more time and labor intensive. Parents could be required to provide a written rationale explaining their decision not to vaccinate their child. Additionally, requiring parents to reapply for exemption status at the beginning of each school year, or requiring all forms to be notarized are two avenues that legislators may consider when proposing new or additional administrative requirements. While it is not necessary to require parents to complete all of the aforementioned steps, having parents complete several steps makes vaccination more convenient, and prevents parents from claiming a nonmedical exemption, as it may be more pragmatic, and in some cases less expensive than opting out of vaccination. These

administrative requirements and procedures serve to "nudge" parents to vaccinate their children, rather than penalize or criticize parents seeking nonmedical exemptions [38].

**Effective Health Communication**

Law based interventions should complement, not replace, effective health communication. Such interventions could require parents to obtain exemption forms from a health care provider or local health department, which would ensure that parents have direct contact with a health care provider or public health professional. However, it is important that educational pamphlets not replace face-to-face meetings with providers, as pamphlets are not a good substitute for in-person meetings with providers [40]. Rational administrative requirements should also help facilitate discussion between parents and providers. This would provide parents with ample opportunities to ask specific questions, while allowing providers to appropriately address each parent's concerns and tailor the discussion to each parent's or patient's needs [41, 42]. Additionally, providers need to be trained on appropriate approaches to better address parental concerns. By using established frameworks to present information and discuss specific vaccinations concerns, providers will be better able to build rapport with their patients, and more importantly gain the trust of parents who are making important immunization decisions [41].

**Financial Incentives and Penalties**

In additional to rational administrative requirements, financial incentives and penalties could be effective in maintaining high vaccination rates among school-age children. While the U.S. federal government cannot impose mandates requiring school-entry vaccination, it can offer financial incentives, such as tax reductions to those who are fully vaccinated. Studies indicate

that financial incentives are effective in promoting simple preventative care [43] and health behaviors for discrete actions such as vaccination [21]. Moreover, taxation is a well-established mechanism to raise revenue, and could potentially be used to encourage or discourage specific behaviors [21]. Generally, speaking there is a strong interest in maintaining high vaccination coverage, and restricting nonmedical exemptions. Financial incentives and penalties are two possible avenues that lawmakers could consider.

Financial incentives have been introduced in other countries to address maintain or increase vaccination rates. For example, in 1997 the Australian government introduced a federal initiative, providing financial incentives for parents who vaccinated their children, and for health care providers who achieved high vaccination coverage in their practices. As a result, immunization coverage among children under the age of 7 increased to over 90% [7, 44]. In recent years, financial incentives for parents and providers have been largely discontinued [45]. Yet tax benefits were still available for parents whose children met minimum eligibility requirements [45]. .However, Australia has recently introduced a new "no jab, no pay" policy. Under this new policy, conscientious objection (philosophical) exemptions will be eliminated, and parents who refuse vaccination will lose thousands of dollars in welfare benefits [46]. Policy makers argue that the choice not to vaccinate is not supported by established medical research or public policy; therefore, opting out of immunization requirements will not be supported by taxpayers.

While financial incentives have been largely effective in Australia, implementing similar financial incentives in the United States may be problematic due to growing skepticism

surrounding vaccines. In fact, financial incentives for families and providers may increase exemption rates, as parents may view these incentives as coercive, and may become suspicious of physicians who receive incentives.

Financial penalties, in the form of taxes, could also be imposed to deter people from opting out of vaccination. Taxes imposed on tobacco products have dramatically reduced consumption while also raising revenue. The World Health Organization reported that increasing taxes in South Africa resulted in fewer people using tobacco products, and of those who continued to use tobacco products they consumed less [47]. Imposing an income-based tax on those who opt-out of vaccination requirements may be an effective means of deterring exemption, without being overtly coercive [21].

By imposing financial penalties on parents who refuse vaccinations for their children, funds could also be levied to help cover the costs of vaccine-preventable disease outbreaks. In 2011, there were 107 confirmed measles cases associated with 16 outbreaks in the United States. These outbreaks required significant resources and personnel time, and the economic burden of these outbreaks was staggering. It is estimated that the total economic burden on local and state health organizations ranged from 2.7 million to 5.3 million U.S. dollars [48]. Collecting taxes to cover the costs of such outbreaks would substantially reduce the economic burden on state and county health departments. While these types of taxes have been proposed to maintain high levels of vaccination coverage and collect funds for outbreak responses, none have been levied, as there are both practical and ethical implications that must be carefully vetted.

## Policy Implementation

As administrative requirements become more involved, it is important that those enforcing compulsory vaccination laws, such as school nurses and administrators, be properly educated ensure that new policies are adhered to. Recently, California passed legislation (AB 2109), which imposes more stringent requirements for claiming nonmedical exemptions. In their examination, Wheeler and Buttenheim considered the self-rated awareness, self-rated knowledge, and specific knowledge of school officials regarding this new legislation. Their findings showed that school officials reported low levels of self-rated awareness and knowledge, and were able to identify select elements of the new legislation [49]. And while school administrators had limited knowledge of the new legislation, the majority was able to identify their school's communication plan, indicating that they have the capacity to implement these new procedures [49]. However, school administrators also identified the need for written materials to inform school staff, as well as parents. Additionally, other materials such as electronic and bilingual materials were also identified as necessary materials to inform staff and parents [49]. Therefore, before new vaccine legislation goes into effect, school administrators, public health officials, and parents must have access to information to improve awareness and knowledge of legislative changes that may affect them.

## Conclusion

Proposed vaccine-related legislation should focus on broadening rational administrative requirements, which would restrict, but not eliminate, nonmedical exemptions. Financial incentives and penalties could also be introduced to restrict nonmedical exemptions, encouraging parents to immunize their children without being overly coercive. Ultimately, these steps will tip

the “balance of convenience” in favor of vaccination, and would serve to remind parents of the importance of vaccination, as well as the risks associated with not vaccinating their children.

**Public Health Implications**

Vaccines are among the most effective public health tools of the 20th Century, having eliminated or greatly reduced the prevalence of many diseases that were once major causes of illness and death [3, 5]. The introduction of vaccines has led to the elimination of measles in the Americas, the elimination of wild-type polio from all but a handful of countries, and the global eradication of smallpox [1]. Since the introduction of routine immunizations in the United States, mortality rates due to diphtheria, pertussis, tetanus, and mumps have decreased by 99% [3]. Moreover, regular use of Hib conjugate vaccines has nearly eliminated Hib invasive disease in infants and children in the U.S. [5].

Vaccination remains the most effective means of preventing and controlling infectious disease outbreaks in the U.S. and abroad. It is critical that we, as a society, maintain a high level of vaccination coverage in order to prevent and control the spread of potentially deadly infectious diseases. School-entry immunization requirements are effective, as they help ensure that nearly all school-aged children are vaccinated, but are also effective in preventing vaccine-preventable diseases [5, 15]. While these laws have been generally well accepted by communities, school administrators, and physicians [5], fervent opposition from various groups has persisted. Parents who choose not to vaccinate their children have cited strong moral convictions opposed to compulsory vaccination, while other cite religious dissonance. Additionally, some parents have expressed concerns regarding vaccine safety and the number of vaccines children receive during childhood.

While vaccination coverage remains high throughout the United States, exemption rates for

nonmedical exemptions has increased, and the rate of increase has accelerated in recent years [27]. Nonmedical exemptions, and the increasing number of exempt children have very tangible consequences for public health. For example, personal beliefs exemptions and nonmedical exemptions that are easy to obtain are associated with higher overall exemption rates, as well as increases in pertussis incidence [50]. Additionally, subsequent outbreaks due to vaccine refusal place a significant economic burden on public health infrastructure [48, 51].

In order to maintain high vaccination coverage, and reduce the number of parents seeking nonmedical exemptions from school-entry immunization requirements, it is critical to implement dynamic and reasonable legislation to "nudge" parents towards vaccination without being overly coercive [17, 38]. Governments have an obligation to protect the common good, and a responsibility to establish laws and regulations to discourage nonmedical exemptions and vaccine refusal [51].

Proposed legislation should aim to restrict, not eliminate, nonmedical exemptions. Legislation must be carefully crafted, weighing individual freedoms against public benefit [7]. Through the incorporation of rational administrative requirements and financial incentives and penalties, legislators can shift the "balance of convenience" towards vaccination, making vaccination the default option [52]. These administrative procedures can also help facilitate discussion between physicians and public health practitioners. As vaccine hesitancy and refusal is becoming more prominent, it is critical that effective communication strategies are developed to address the importance of immunization [5]. By requiring parents to meet with a health care provider, parents will be presented with accurate information in an appropriate manner. Ideally, the

inclusion of rational administrative requirements, and financial incentives and penalties in new vaccine-related legislation will reduce the number of nonmedical exemptions, helping to ensure that only parents who are truly opposed claim exemptions.

As the number of nonmedical exemptions continues to rise, it is critical that new legislation is passed to restrict nonmedical exemptions. Without such legislation, the number of parents seeking nonmedical exemptions is likely to increase, having dangerous consequences. It is critical that to maintain high immunization coverage, as it is essential to sustain herd immunity and protect communities from infectious diseases that have the potential to cause significant morbidity and mortality [17].

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