MANDATING THE HPV VACCINE AS A SCHOOL ENTRY REQUIREMENT:
ETHICAL AND POLICY CONSIDERATIONS

BY

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DEDICATION AND ACKNOWLEDGEMENTS

For my mother, who has always taught me that I can be anything I want to be, and who has always allowed me to be in charge of my own life.

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ABSTRACT:

MANDATING THE HPV VACCINE AS A SCHOOL ENTRY REQUIREMENT:
ETHICAL AND POLICY CONSIDERATIONS

Thesis under the direction of Ana Iltis, Ph. D., Associate Professor of Philosophy and
Director of the Center for Bioethics, Health and Society

Mandating the HPV vaccine is very controversial because although eliminating
cervical cancer is a worthwhile cause, a variety of issues come into play with the HPV
vaccine that our nation’s public health officials have yet to encounter in any other
vaccine, prompting a re-evaluation of the proper role of vaccine mandates. This thesis
evaluates what makes the HPV vaccine different from previously mandated vaccines,
offering an analysis of the proposed HPV vaccine mandates and arguing that the vaccine
does not provide sufficient public health benefit to justify overriding individual autonomy
for the sake of the public good. Although the HPV vaccine confers prospective benefit in
the form of prevention of HPV-derived cancers to those who receive it, there is not
enough of a public health necessity to justify imposing the high financial and moral costs
of vaccination on the public. Because the potential burdens of an HPV vaccine mandate
can be minimized through alternative, voluntary vaccination programs that confer similar
public health benefits as mandates without coercion, and because in the absence of a
public health necessity, it is unfair and unjust to impose the burdens of a vaccine mandate
on the public, HPV vaccine mandates are not the ideal legislative solution.
CHAPTER ONE

THE ETHICS OF COMPULSORY PUBLIC HEALTH MEASURES IN GENERAL
AND VACCINE MANDATES IN PARTICULAR

Introduction

The goal of public health policy is to improve the nation’s health for the betterment of society. Vaccines are one of the greatest, if not the single greatest, public health achievements of human history: they significantly enhance the human capacity to prevent infectious disease. Before the advent of vaccines in the nineteenth century, infectious diseases like smallpox, yellow fever, measles, mumps, polio, diphtheria, tetanus, pertussis, rubella, and Hib infected and killed thousands of people each year, the vast majority of the casualties being children. Smallpox alone “killed more people than the Black Death and all the wars of the twentieth century combined; about five hundred million people died from the disease” (1). The smallpox vaccine was the first vaccine developed (in 1796) and it was also the first vaccine to be mandated. Today, we have vaccines against almost every infectious disease on earth, and most states mandate that children receive multiple vaccines before they can attend public school. The result of state-enforced vaccine mandates has been a dramatic decline in the incidence of infectious diseases in the United States.

However, the vaccine landscape is changing as we learn more about viruses and how they function. In 2008, the Nobel Prize in Physiology and Medicine was awarded in equal halves to Harald zur Hausen for his discovery of the causal role of human
papilloma viruses (HPV) in cervical cancer and to Françoise Barré-Sinoussi and Luc Montagnier for their discovery of the human immunodeficiency virus (HIV) (2). Hausen’s discovery of how HPV causes cervical cancer, the world’s second leading cause of cancer deaths in women, led to the development of the first HPV vaccine, Gardasil. When Gardasil was released by Merck in December 2005, approved by the Food and Drug Administration (FDA) in June 2006, and recommended by the Advisory Committee on Immunization Practices (ACIP) less than a month later, legislative proposals were made for school-entry HPV vaccine mandates in several US states (3, 4). The proposed mandates ignited heated social, political, and moral debates covering a range of issues. As of 2011, only Virginia and the District of Columbia have passed school-entry mandates for the HPV vaccine, while all other legislative proposals have been suspended or rejected as a result of the controversies surrounding the HPV vaccine (3, 4).

Why is the HPV vaccine so controversial? Surely, eliminating cervical cancer is a worthwhile cause. However, a variety of issues come into play with the HPV vaccine that our nation’s public health officials have yet to encounter in any other vaccine, which has prompted a re-evaluation of the proper role of vaccine mandates. This thesis will evaluate what makes the HPV vaccine different from previously mandated vaccines, offering an analysis of the proposed HPV vaccine mandates and arguing that the HPV vaccine does not provide sufficient benefit to the public to justify overriding individual autonomy for the sake of the public good because HPV-derived cervical cancer does not constitute a public health necessity in the United States.
Public Health vs. Individual Autonomy

In order to analyze the balance between benefitting the public good and respecting individual autonomy in the context of the HPV vaccine, we must first understand what exactly is being balanced—what is autonomy, what is the public good, and what criteria should be used to determine which is more important in a given situation? Also, who gets to do the balancing, i.e. how are public health measures enacted, implemented, and enforced? How should we, as a society, define the limits of individual autonomy, liberty, and choice? To what extent do citizens have a duty to prevent harm to other citizens? Specifically regarding the HPV vaccine, when parents refuse to vaccinate their child against HPV, are they causing unjustifiable harm to others? When a young woman chooses for herself to refuse the HPV vaccine, is she causing unjustifiable harm to others? Does the lack of accessibility to the HPV vaccine for boys and young men represent an unjustifiable harm to that population? Would state mandates requiring the HPV vaccine for school entry cause unjustifiable harm or prevent citizens from living autonomously? These more specific questions about the HPV vaccine will be addressed in detail later. First, I will consider the meaning of the balance a society must maintain between individual autonomy and the public welfare.

Respect for autonomy is a paramount value in bioethics. Beauchamp and Childress, who first articulated a principle of respect for autonomy as a foundational obligation in bioethics, define autonomy as encompassing “at a minimum, self-rule that is free from both controlling interference by others (liberty) and from certain limitations such as an inadequate understanding (agency) that prevents meaningful choice” (5). In an ethical society, autonomous persons are respected as capable of making their own
decisions about many aspects of their lives, a view embodied by the principle of respect for autonomy. The use of power to override a competent person’s autonomous decision for the person’s own welfare is paternalistic because it fails to respect the authority of the individual over himself and asserts that another is more capable of making good decisions for that individual than he or she is (6). However, public health programs are not paternalistic because they do not override an individual’s autonomy for the sake of that individual; rather, they override an individual’s autonomy for the sake of the public welfare. Public health programs, therefore, are not justified or unjustified based on the principle of paternalism. Rather, public health programs rely on social contract theory and the harm principle. Citizens of a just society abide by a social contract wherein they exercise their own autonomy insofar as they are not causing unjust harm to others. Social contract theory is based on the idea that in a civil society, citizens forfeit some of their autonomy in exchange for the benefits of existing within a civilized society: “Communities all exist based on some degree of an underlying social contract- without agreement, a fundamental notion of obligation and organization, there cannot be a community” (6). Society relies on its members abiding by the social contract in order to function, which is for the benefit of its members and the society as a whole. John Stuart Mill argued that “society should permit individuals to develop according to their own convictions, as long as they do not interfere with a like expression of freedom by others or unjustifiably harm others” (5). According to Mill’s argument, which is commonly referred to as the harm principle, citizens of a just society may make autonomous decisions about their own lives insofar as they do so without causing unjustifiable harm to others or interfering with other citizens’ freedom to live autonomously.
There are circumstances that so endanger members of a community that the benefit of protection outweighs losing one’s autonomy. For example, stricter security measures during war times place burdens on citizens and strip them of certain liberties, but the society as a whole, and each individual in it, benefits from the protection that stricter security measures provide. Some infectious diseases represent this significant a threat to society because they are casually communicable, meaning they are spread through breathing or casual contact including shaking hands and other every day interactions.

When too many members of a community are susceptible to a casually communicable infectious disease, a single infection can become an epidemic, claiming lives and significantly reducing societal productivity. Before the advent of vaccines, the only way to protect society from casually communicable infectious diseases was through quarantines, which arguably restricted individual autonomy to a far greater extent than vaccine mandates do today. Thanks to vaccine mandates, most American children are immune to common infectious diseases, and most children who are not vaccinated are protected against communicable diseases by herd immunity, the phenomenon whereby a population is protected against a disease if enough members have immunity, even if not every single member has immunity. Herd immunity is important because some children cannot receive vaccines for medical reasons and not all children who are vaccinated will mount a sufficient immunologic response to give them immunity to the disease. This is because no vaccine is one hundred percent effective: vaccines induce immunity in about 85-95% of recipients (1). Herd immunity is critical to maintaining public health, but some parents choose not to vaccinate their children so that they can “hide in the herd,”
avoiding the risks of vaccination and enjoying the benefits of herd immunity. The problem arises when too many parents choose not to vaccinate and herd immunity diminishes, making those for whom vaccination is not an option (such as children with medical contra-indications like leukemia) vulnerable to infectious diseases. Those who refuse to vaccinate their children endanger herd immunity, thereby endangering others in the community in which they live. Parents who refuse vaccination tend to cluster, and as a result there are communities in the United States that lack herd immunity against communicable diseases. In these communities where a large percentage of parents choose not to vaccinate their children, communicable disease can pose a very real danger for many children- those whose parents elected not to get them vaccinated, those who could not get vaccinated for medical reasons, and those who were vaccinated but did not mount a sufficient immunologic response and are still susceptible. Social patterns of vaccine refusal create geographical pockets of vulnerable children: in 2007, some counties in Washington state had non-medical vaccine exemption rates as high as 26.9% (7). This is highly problematic, especially in light of the fact that measles outbreaks in Colorado schools have been associated with exemption rates as low as 4.3% and nationwide data show that non-vaccinated children are 35 times more likely to contract measles as vaccinated children (7). In fact, exemption rates as low as 2% have been associated with increased risk of communicable disease in a community (7). Unvaccinated children also pose a potential threat to the larger community that may suffer from the effects of an outbreak or an epidemic of communicable disease. For these reasons, casually communicable infectious diseases pose a significant risk to communities and it is justifiable to limit the individual’s right to autonomously refuse
immunization. Herd immunity provides a compelling reason for overriding individual autonomy for the sake of the public good; it is a perfect example of an instance when one citizen exercising his or her rights (in refusing vaccination) may unjustly endanger another citizen (with the threat of infectious disease). This is part of why vaccine mandates are considered just and ethical.

When considering any requirement that a society will place on its citizens, a balance must be struck between individual autonomy and the collective good. The preservation of individual autonomy is sometimes overridden by the duty to do no harm, or nonmaleficence. This is perhaps nowhere more clear than in the realm of public health, particularly where vaccine mandates are concerned. Vaccine mandates provide a powerful example of the need for society to use authority to overcome individual autonomy in order to protect the society from harm. However, the HPV vaccine is different from previously mandated vaccines, partially because HPV is not casually communicable. HPV is spread through sexual contact with an infected individual, and therefore when a parent refuses to vaccinate their child against HPV, they are not causing unjustifiable risk of harm to others since others would have to engage their child in a sexual relationship, which is a choice unlike breathing or casual contact, in order to be at risk of HPV infection. Similarly, when a young woman chooses for herself to refuse or accept the HPV vaccine, she isn’t causing unjustifiable risk of harm to others in her community in either instance. The duty to do no harm to others does not support an HPV vaccine mandate because a failure to get the vaccine does not constitute an unjustifiable risk of harm to others.
Vaccine Mandates

In the United States, the FDA “has regulatory authority to license vaccines based on information regarding safety, immune response and efficacy submitted by the manufacturer” (4). The Centers for Disease Control and Prevention (CDC), a branch of the Department of Health and Human Services, makes recommendations regarding vaccine use following FDA approval through the ACIP (4). The ACIP consists of fifteen voting members with expertise in a variety of fields related to immunization and the control of vaccine-preventable diseases (8). The secretary of DHHS appoints the fifteen voting members from a pool of nominees (8). The committee also has “8 ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 26 non-voting representatives of liaison organizations that bring related immunization expertise” (8). The ACIP issues recommendations regarding vaccination schedules for children, adolescents, and adults annually through the Morbidity and Mortality Weekly Report’s Recommendations and Reports series (4). ACIP recommendations set the bar for the national standard of care: many medical professional organizations adhere to ACIP recommended vaccine schedules, states often reference ACIP recommendations to make legislative decisions about vaccine mandates, and insurance companies often make decisions about whether or not to cover the cost of a vaccine based on ACIP recommendations. Additionally, the federal government purchases ACIP recommended vaccines for distribution to Medicaid-eligible and uninsured or underinsured children through the Vaccines for Children Program (9). The ACIP’s review process includes:
1. a review of the FDA labeling/package inserts for each vaccine.;
2. a thorough review of the scientific literature (both published and unpublished, when available) on the safety, efficacy, acceptability, and effectiveness of the immunizing agent, with consideration of the relevance, quality, and quantity of published and unpublished data;
3. an assessment of cost-effectiveness;
4. a review of the morbidity and mortality associated with the disease in the population in general and in specific risk groups;
5. a review of the recommendations of other groups;
6. a consideration of the feasibility of vaccine use in existing child and adult immunization programs. Feasibility issues include, but are not limited to, acceptability to the community, parents, and patients; vaccine distribution and storage, access to vaccine and vaccine administration, impact on the various health care delivery systems, population distribution effects, and social, legal, and ethical concerns. (3)

It is clear from their review process that the ACIP conducts a thorough analysis of a vaccine before recommending it for inclusion in vaccine schedules. However, the ACIP does not issue or implement mandates; that responsibility lies with the states.

The ACIP added the HPV vaccine to its list of suggested childhood vaccinations on June 29, 2006. Dr. Jon Abramson, a pediatric infectious disease specialist, was the chair of the ACIP when the committee recommended the HPV vaccine (10). In an interview conducted at Wake Forest University Baptist Medical Center, where he
currently serves as the chair of Pediatrics, Dr. Abramson said that the ACIP had no trouble at all recommending the HPV vaccine based on the process described above, but when Dr. Abramson formed a sub-committee and charged it with coming up with a recommendation as to whether states should mandate the HPV vaccine for girls entering sixth grade, the sub-committee was unable to do so (10). Dr. Abramson said that even those on the committee in favor of state mandates for the HPV vaccine had concerns about the cost of the vaccine and were opposed to children being kept out of school because their parents couldn’t afford it (10).

Dr. Abramson also shared his personal opinion: he doesn’t support state mandates of the HPV vaccine for several reasons. First, HPV isn’t transmissible in a school setting. Second, states would have to provide financial support for vaccination programs so that children whose parents couldn’t afford the vaccine and were ineligible for federal health care programs (Medicaid and Vaccines for Children) could get the vaccine in order to attend school; finally, it is yet to be seen if vaccine uptake will rise to a point at which there isn’t a need for mandates, though uptake levels among the recommended age group are currently at about 25%, too low for herd immunity and certainly low enough to support incentives for vaccination such as public education and mandates (10, 11). Dr. Abramson’s reasons for opposing a school mandate for the HPV vaccine highlight the most interesting issues this vaccine raises: Does a disease have to be transmissible in a school setting for a school-entry vaccine mandate to be ethical? Do parents have a greater right to refuse prophylactic treatment for a sexually transmitted infection for their child than they do for other types of infections? Do we, as a society, want to invest in expensive vaccines for many to prevent even more expensive cancer treatment for a few?
Does a gender-specific mandate violate civil rights? Does the public have the responsibility to bear the burden of public health measures to prevent a disease that is also preventable through behavior modification?

This thesis will consider whether or not mandating the HPV vaccine as a school-entry requirement is ethical, using the assumption that an ethical vaccine mandate provides a public health benefit that justifies overriding individual liberty and choice. Chapter 2 will describe the scientific basis for vaccine mandates: the epidemiology of HPV and cervical cancer in the United States and the biological functioning of HPV and the vaccine. Chapter 3 will evaluate United States legal precedents for vaccine mandates and discuss how HPV vaccine is similar to and different from other vaccines that have been mandated successfully. Chapter 4 will address public concerns and misconceptions about vaccines in general and the HPV vaccine in particular, providing a close look at the growing anti-vaccine movement in the United States. Finally, chapter 5 will offer policy suggestions, concluding that mandating the HPV vaccine as a school-entry requirement in the United States is not an ethical course of action for states since there is no public health necessity for an HPV vaccine mandate and a failure to vaccinate against HPV does not present an unjustifiable risk of harm to others in one’s community.
References, Chapter 1


CHAPTER TWO

THE IMPETUS FOR HPV VACCINE MANDATES: HPV AND CERVICAL CANCER
EPIDEMIOLOGY, VACCINE SAFETY, EFFICACY, AND COST

The Impetus for Vaccine Mandates

Because the goal of vaccine mandates is to protect the public health, it would be counter-productive to mandate a vaccine that does not safely and effectively target a disease that affects the population in a substantial way. Furthermore, because the benefit/risk balance is harder to identify for prophylactic than for therapeutic measures, the benefits of vaccination should clearly exceed the risks for the population that is required to receive the vaccine. This chapter will evaluate the disease burden of both HPV and HPV-derived cancers in American women and men and will explore the biological functioning of the HPV virus in order to convey an appreciation of how HPV infection leads to cancer, as well as how the HPV vaccine prevents infection and cancer. Clinical trials and studies that have evaluated the efficacy and safety of the HPV vaccine will be described. All data herein are based solely on HPV epidemiology in the United States since the task at hand is to evaluate the ethical appropriateness of a vaccine mandate in the United States.

Disease Burden of HPV and Cervical Cancer in the United States

Human Papilloma Virus is the most common sexually transmitted infection (STI) in the United States (1). An estimated 20 million people, or 15% of the population are
currently infected, and 6.2 million Americans are newly infected with HPV each year. It is estimated that 80% of sexually active American women will be infected with HPV before age 50 (1). The highest infection rates are among young women under the age of 25. Incidence rates in this age group range from 28% to 46% (1). Incidence is also extremely high among adolescents: among those with only one or two sexual partners, infection rates range from 10% to more than 25%, more than any other STI (1).

Adolescents and young adults are at a much greater risk of contracting HPV than any other faction of the population for both sociological and biological reasons (2). Adolescents and young adults are more likely than other groups of people to have unprotected intercourse, to have multiple partners, to be infected with others STIs, to engage in substance abuse, to use oral contraceptives, to have inadequate access to medical care, and to lack knowledge of safe sex practices (2). Additionally, young women produce less cervical mucus and are more prone to local tissue tearing during intercourse than older women, both of which encourage HPV infection (2).

A very small number of HPV infections result in the development of cervical cancer. The disease burden of cervical cancer in the United States has been greatly reduced thanks to regular screening. Current guidelines suggest that women get Papanicolaou (Pap) tests at least every other year (3). Pap tests involve taking a scraping of cervical epithelial cells for histological examination to find abnormal and pre-cancerous cervical cells (3). If a Pap test reveals any abnormal histology in a woman over 21, HPV DNA testing is conducted in a follow-up visit by taking a second sample of cervical epithelial cells and testing for the presence of viral DNA (3). If HPV DNA is found in women who also have abnormal cervical epithelial cell histology, a colposcopy
is performed on the patient, allowing the physician a magnified view of the cervical tissue for diagnostic purposes (3). If cervical cancer or cancer precursors are identified, treatment options include laser removal of cervical lesions, which is recommended in younger women, and electrosurgical excision of the cervix, which is recommended in older women (3). In women aged 20 years or younger, cytology screening is suggested every six months if a Pap test is abnormal since the incidence of HPV is so high in this population and it often clears on its own (3).

Cervical cancer is the second most common cancer in women worldwide, but it is only the seventh most common cancer among women living in developed countries, and it is not among the top ten most common cancers among women in the United States (4, 5). In the United States, cervical cancer morbidity is currently 8.9 per 100,000 women and mortality is 2.7 per 100,000 women (4). It is estimated that each year in the United States, 10,800 new cases of HPV-associated cervical cancer are diagnosed and that 4,100 women die from cervical cancer (6). Semi-annual Pap tests and subsequent follow up for abnormal findings have reduced the burden of cervical cancer in developed countries (4). Despite the success of regular screening, there are significant racial, ethnic, and geographical disparities in morbidity and mortality of cervical cancer among American women (4). Morbidity and mortality are both significantly higher among black and hispanic women than among white, non-hispanic women (4). Cervical cancer is the eighth most common and tenth most deadly cancer among African American women, and the seventh most common and tenth most deadly cancer among Hispanic women in the United States (7). Additionally, cervical cancer mortality is higher among women living in the South than women living in the Northeast (4). These disparities may be
attributable to lower rates of Pap screening and follow up for cervical lesions or abnormal test results (4).

Although cervical cancer is the most common HPV-associated cancer, HPV can also cause cancer of the anus, vagina, vulva, penis, tongue, and throat. It is estimated that HPV is responsible for approximately 85% of anal cancers (anal cancers have an incidence of < 2/100,000 people), 70% of vaginal cancers (vaginal cancers have an incidence of < 1/100,000 women), 40% of vulvar cancers (vulvar cancers have an incidence of < 2/100,000 women), and 40% of penile cancers (penile cancers have an incidence of < 1/100,000 men) (6). The incidence of these other HPV-associated cancers pale in comparison to the incidence of cervical cancer, and for this reason the scientific literature is focused on HPV-associated cervical cancer. HPV-associated cancers in men have not enjoyed much attention from the scientific and medical community until recently. A recently published clinical trial on the efficacy of HPV vaccination in men may be found in the “vaccine efficacy” portion of this chapter.

**Human Papilloma Viruses**

Papilloma viruses, like all viruses, mimic life without actually being alive. They are similar to living organisms because they have genomes and proteins, but they can’t replicate on their own and must infect host cells in order to complete their reproductive cycle. Human Papilloma Virus is a small, naked (lacking an envelope) virus with a circular double stranded DNA genome. Unlike many viruses that have single- or double-stranded RNA genomes or single stranded DNA genomes, papilloma viruses have a genome that is, in many ways, just like ours- the human genome is also made up of
double stranded DNA (8). Because the papilloma virus genome is structurally identical to the human genome, the viral genome can integrate into the cellular genome during the viral replication process in the nucleus of a human cell (8). Integrating into the host cell genome is not a natural part of the replication cycle of papilloma viruses, and it does not benefit them. In fact, genome integration is a dead-end for the virus because it prevents them from replicating and creating new virions—new viruses that will leave the host cell to infect healthy, nearby cells (8). When the papilloma virus genome integrates into the host cell genome, cancer can develop (8). This will be discussed in more detail later.

The normal life cycle of the human papilloma virus will first be examined.

The first step in viral infection is attachment to a healthy host cell. For HPV, a host cell is a basal stem cell of the human epithelia. Because HPV requires basal epithelial cells to successfully infect, a cut or abrasion must be present in the skin in order for the virus to have access to an appropriate host cell (8). The virus attaches to a protein called integrin that is found on the surface of all healthy basal epithelial cells (8). The virus then enters the cell via a process called receptor-mediated endocytosis, which essentially entails the cell swallowing the virus whole. Once the virus is inside the cell, cellular enzymes break down the capsid protein package that contains the viral genome inside, thereby releasing the viral genome into the cell (8). A nuclear localization signal that is found on an inside portion of the capsid helps the viral genome get to the host cell’s nucleus, where the virus uses a small number of viral genes to hijack the host cell’s DNA replication machinery and use it to make new virions, new copies of the virus that can infect healthy host cells once they are released (8). HPV has to use the host cell’s DNA replication enzymes because it doesn’t have genes that code for the proteins.
necessary for replication, specifically, HPV doesn’t code for its own DNA polymerase (8). However, since HPV infects undifferentiated basal cells that normally don’t express the replication machinery needed, HPV must induce S phase, the cellular replication phase of the cell cycle, in its host cell (8). E7 is an HPV early gene that codes for proteins that induce S phase in the host cell by binding to the cellular transcription factor Rb, or retinoblastoma, a transcription factor that is required for healthy cellular replication and division (8). In a healthy human cell, Rb is the control mechanism for cellular replication (8). Rb works by binding to a cellular transcription factor called E2f, which is required for expression of all the cellular replication enzymes (8). When Rb binds to E2f, transcription can’t occur and therefore cellular replication and division can’t occur (8). HPV E7 proteins bind to Rb, preventing Rb from binding to E2f, thereby allowing transcription to occur and inducing the cellular division process called S phase (8). Once in S phase, basal epithelial cells begin to divide and differentiate, moving up through the epithelium and producing more and more daughter cells and simultaneously more and more copies of the HPV genome (8). In differentiated cells, late viral proteins involved in virion assembly are expressed and viral genome replication is exponentially increased (8). Normally, DNA replication in a differentiated cell would trigger apoptosis via p53, the cellular tumor suppressor protein (8). In a healthy human cell, p53 acts as a tumor suppressor by inducing apoptosis and cell death when it becomes activated by the presence of abnormal DNA replication activity (8). However, HPV has an early gene called E6; E6 proteins bind to and prevent activation of p53 (8). This prevents the host cell from recognizing that the virus is replicating using the cell’s machinery (8). There is an instability sequence in the mRNA of E6 and E7 (8). RNAses can bind to this
instability sequence and prevent transcription of E6 and E7 genes, thereby preventing E6 and E7 proteins from binding to p53 and Rb, respectively (8). This causes the host cell to stop replicating and dividing, and explains why normal HPV infection doesn’t lead to cancer (8).

HPV-associated cancer of the human epithelium develops when the HPV genome integrates into the human host cell genome (8). Integration happens by random chance while the viral genome is inside the nucleus of the human host cell through a process called homologous recombination (8). This is possible due to the double stranded DNA structure of the HPV genome, which matches the double stranded DNA structure of the human genome. Homologous recombination is normal in the human cell, but when the viral DNA is present, homologous recombination can result in the viral DNA integrating into the host cell genome (8). Integration does not benefit the virus and actually prevents the virus from accomplishing its goal of making new virions (8). Because homologous recombination is random, the instability sequence that controls E6 and E7 can be lost in integration, although this doesn’t always happen (8). When the instability sequence is lost in integration, E6 and E7 are “on” all the time (8). The result is that p53, the tumor suppressor, is always “off” and Rb, the control mechanism for human cellular replication and division, is always “off” (8). This leads to uncontrolled cell division and cancer (8).

There are several strains of HPV. Some strains infect the hands and feet, others the oral cavity. Those that infect the genital tract, of which there are many, are categorized according to the risk infection poses: low risk for cancer (responsible for genital warts): types 6, 11; moderate risk for cancer: 33, 35, 39, 40, 43, 45, 51, 52, 53, 54, 55, 56, 58; high risk oncogenic potential: 16, 18 (4). HPV types 16 and 18 account for
70% of HPV-derived cancers (8). The strains of HPV that cause cancers of the anogenital region are transmitted from person to person via intimate sexual contact of any kind: oral, vaginal or rectal involving either heterosexual or homosexual partners (3). It’s important to note that due to the nature of evolution, if the niche occupied by HPV strains 16 and 18 were vacated due to high levels of vaccination, other oncogenic strains could come to occupy that niche, causing more cancers than they currently do (8). This is one reason that more longitudinal data is needed on the HPV vaccine that protects against strains 16 and 18.

**The HPV Vaccine**

There are a few different ways to make a vaccine. To protect against a virus, there are live attenuated vaccines, inactivated or “killed” vaccines, and virus-like particle vaccines. Other types of vaccines protect against bacterial infections and will not be discussed. Live attenuated virus vaccines are made by infecting an animal or a cell line in a lab with the virus and allowing it to attenuate, or mutate over and over for a very long time so that the genome is different and no longer harmful (8). These vaccines produce a very good immune response because they activate both a B cell and a T cell response from the human immune system. Live attenuated virus vaccines do, however, pose a risk of conferring the disease that the vaccine is designed to protect against because attenuation can be reversed by random genetic mutation (8). The Sabin oral polio vaccine is an example of a live attenuated virus vaccine that poses risk of causing polio. Inactivated or “killed” virus vaccines involve making the virus unable to infect and then injecting either the whole inactivated virus or some part of it (13). These
vaccines induce only a B cell response (no T cell response) and therefore confer less immunity than live attenuated vaccines (8). However, since the inactivation of the virus is irreversible, these vaccines pose no risk of conferring the disease they protect against and are therefore safer. The Salk polio vaccine, which is injected rather than orally administered, is an example of an inactivated virus vaccine. The Salk polio vaccine is now used in the United States instead of the Sabin oral polio vaccine since polio was eliminated in the US by the widespread administration of the Sabin vaccine throughout the mid to late twentieth century (13). Once domestic polio was eliminated, the only cases of polio in the US were caused by either reverting of the Sabin vaccine or cases that were contracted abroad, so the switch was made in 1998 to the Salk vaccine (largely thanks to advocacy by a father whose son developed polio after receiving the Sabin vaccine) because although it confers less immunity, it is safer and poses no risk of causing polio in vaccinated children (9).

The newest type of vaccine that protects against viruses is a virus-like particle vaccine. These vaccines are particles that look just like the real virus to the immune system but do not contain the viral genome (8). The HPV vaccine is the first virus-like particle vaccine. It mimics the constructed shape of the HPV capsid, which is formed by repeating units of L1, the capsid protein that encases the viral genome. Recombinant DNA technology is used to make this vaccine by inserting the viral gene that codes for the L1 protein into a plasmid and inserting the plasmid into yeast cells so that when the yeast cells reproduce, they make abundant copies of L1 protein, which self assemble into a virus like particle (9). A virus like particle vaccine is preferable for the HPV vaccine because a vaccine that included viral DNA (a live attenuated vaccine) would pose risk of
development of cancer since cancer develops when the viral genome integrates into the cellular genome (8). The creation of a virus-like particle vaccine requires the use of eukaryotic cells and careful temperature maintenance, making the manufacturing process expensive. However, this technology produces a vaccine with only one protein per viral strain for the immune system to learn to recognize, so it is very efficient in terms of immunity gained per protein recognized and antibody produced.

The Gardasil vaccine made by Merck, the first HPV vaccine to be approved by the FDA in June 2006, is a quadrivalent virus-like particle vaccine that protects against HPV types 6, 11, 16, and 18. HPV types 16 and 18 have been shown to cause 70% of cervical cancers and HPV types 6 and 11 have been shown to cause 90% of genital warts (which have an estimated annual incidence of 100 per 100,000 people in the United States) (10, 11). Approved by the FDA in October 2009, Cervarix, made by Glaxo-SmithKline, is a bivalent virus-like particle vaccine that protects against HPV types 16 and 18 (12). Cervarix is a virus-like particle vaccine like Gardasil, but it contains an adjuvant absent from Gardasil that GlaxoSmithKline claims confers immunity for a longer period of time. This has yet to be proven through clinical trial, as both vaccines are known to confer immunity for a minimum of five years. The safety and efficacy data for Cervarix so far is very similar to that of Gardasil, with the exception that Cervarix is bivalent and therefore does not confer immunity against HPV strains 6 and 11 as Gardasil does.

**Efficacy of the HPV Vaccine**

Several clinical trials have been conducted to evaluate the efficacy of the HPV vaccine. Rambout, Hopkins, Hutton, and Fergusson conducted a systematic review of the
evidence from all randomized controlled trials that had been conducted through June 2007 (5). Their goal was to “determine whether women who receive the prophylactic HPV vaccination have a lower incidence of persistent HPV infection and precancerous cervical lesions than women who are not vaccinated” (5). This systematic review included all randomized controlled trials with the goal of assessing the efficacy of prophylactic HPV vaccination in women, published and unpublished, throughout the world. They did not include data from trials on therapeutic use of the vaccine, which would entail vaccinating women with current HPV infection (5). The end point Rambout et al required in studies for their review was the World Health Organization and FDA’s recommendation of high grade cervical intraepithelial neoplasia (high-risk pre-cancerous cells of the cervix) as a surrogate outcome for cervical cancer. Six studies were identified that fit all of these criteria, three phase II and three phase III clinical trials. Rambout et al found that across these six clinical trials, prophylactic HPV vaccination was effective at reducing high-grade cervical lesions, persistent infection, low-grade cervical lesions and genital warts caused by HPV types included in the vaccine as compared with control groups (5). The majority of the adverse events reported in the trials reviewed were minor, and reports of serious adverse events and death were similar between the vaccine and control groups in all the trials reviewed (5).

As Rambout et al’s findings demonstrate, previous clinical trials have found prophylactic HPV vaccination to effectively prevent HPV infection and cervical lesions attributable to the four HPV strains included in the vaccine (5). Since the FUTURE I and FUTURE II trials had not reported all of their results at the time Rambout et al conducted their systematic review and since the FUTURE trials have been the largest and most
comprehensive clinical trials conducted on the HPV vaccine to date, they merit a closer
look. The FUTURE I and FUTURE II trials (Females United to Unilaterally Reduce
Endo/Ectocervical Disease) are both currently ongoing, randomized, placebo-controlled
trials that use rates of anogenital and/or high grade cervical intraepithelial neoplasia 3
years-post vaccination as the end-point (13, 14). High grade cervical intraepithelial
neoplasia is used as a surrogate outcome for cervical cancer because it would be unethical
to allow identified pre-invasive lesions to progress to cancer (15). For this reason, study
participants in whom pre-invasive lesions were found were notified and treated (15). The
FUTURE I trial, which enrolled 5,455 women between 16 and 24 years of age, found that
the vaccine reduced the rate of all genital lesions, independent of causal HPV type, by
34% compared to the control arm, and that the vaccine reduced the rate of cervical
lesions, once again irrespective of causal virus strain, by 20% (13). The study also found
the vaccine to be 100% effective at protecting against primary infection (in participants
with no future exposure to the viral strains included in the vaccine) with HPV 6, 11, 16,
and 18 (13). The FUTURE II trial, which enrolled 12,167 women between the ages of 15
and 26 years, found the vaccine 17% effective in reducing all high-grade cervical lesions,
regardless of HPV causal type (14). The study also found the vaccine to be 98% effective
at protecting against primary infection with HPV 6, 11, 16, and 18 (14). The vaccine was
also found to be safe, with the most common adverse events being pain and swelling at
the injection site (14). Across both trials, 6 participants out of 17,622 total participants
reported serious adverse events related to the vaccine, a prevalence of 0.03% (13, 14).
The most common adverse events reported included gastroenteritis, headache,
hypertension, injection-site pain, and a decrease in joint movement at the injection site.
There were no deaths that were related to the vaccine or placebo in either trial (13, 14).

These data reflect results gathered from the entire study population, but relevantly, 93% of study participants in the FUTURE trials were non-virgins (13, 14). This is relevant because the vaccine demonstrated only 17% efficacy in reducing high-grade cervical lesions among women who had evidence of previous exposure to the HPV strains included in the vaccine (a therapeutic vaccination population). Data from participants with no previous exposure to the HPV types included in the vaccine (a prophylactic vaccination population) demonstrated nearly 100% efficacy at preventing cervical lesions (13, 14). Thus, the FUTURE trials demonstrated that the HPV vaccine is most effective as a prophylactic vaccine. Reliable evidence suggests that 25% of American youths have had sex by age 15, 48% have had sex by age 17, and by age 19, this percentage jumps to 70% (16). The combination of the data on the efficacy of the vaccine in HPV-naïve populations and the data on adolescent sexual behavior leads to the conclusion that the vaccine would be most effective at preventing cervical lesions and cervical cancer if it is received before the age of 15. This data has led to the recommendation that girls receive the vaccine at 11 or 12 years of age, before they begin having sex to ensure the vaccine’s prophylactic role in preventing HPV infection.

In February 2011, Giuliano, Palefsky, and Goldstone et al published a study in the *New England Journal of Medicine* reporting their findings on the efficacy of quadrivalent HPV vaccination at preventing HPV infection and disease in males (17). This is the first large randomized, controlled clinical trial that focused exclusively on the efficacy of the HPV vaccine in males. They enrolled 4,065 healthy boys and men aged 16 to 26 years
into a randomized, placebo-controlled, double-blind trial (17). None of the enrollees had more than five lifetime sexual partners and both homosexual and heterosexual boys and men were included (17). There were two study groups: an intention to treat population that received either vaccine or placebo regardless of prior HPV status and a per-protocol population that received either vaccine or placebo and were HPV negative at enrollment (17). In the intention to treat population, the vaccine showed 65.5% efficacy at reducing anogenital lesions resultant from HPV types 6, 11, 16, and 18 and 47.8% efficacy at preventing persistent HPV infection with HPV types 6, 11, 16, and 18 (17). In the per-protocol group, which received the vaccine prophylactically, the vaccine showed 90.4% efficacy at reducing anogenital lesions resultant from HPV types 6, 11, 16, and 18 and 85.6% efficacy at preventing persistent HPV infection with HPV types 6, 11, 16 and 18 (17). This data suggests that the HPV vaccine is just as effective at preventing persistent HPV infection and anogenital lesions in men as it is in women (17). This is significant since men have similar incidence rates of HPV infection to women, though the incidence of HPV-associated anogenital cancers in men is lower than that of cervical cancer in women. However, the development of genital warts due to HPV types 6 and 11 can be physiologically and psychologically harder on men than on women (17).

There are limitations on what can be known about the efficacy of the HPV vaccine. Currently, the duration of immunity conferred by the vaccine is unknown. Clinical trials have demonstrated that the vaccine confers immunity for a minimum of five years. Long-term studies are needed to know how long immunity actually lasts and whether or not booster shots are necessary (12). Additionally, the true effect of vaccination on cervical cancer incidence is still unknown since high grade cervical
lesions were substituted as an outcome of cervical cancer in clinical trials due to the issue of it being ethically unacceptable to allow trial participants to progress to cancer (12). The effect of vaccination on older populations of women has yet to be soundly demonstrated, though clinical trials to date have suggested efficacy in older women approaching that of the demonstrated efficacy in young women with previous HPV infection (12). A major concern is that cervical cancer Pap test screening guidelines will change due to widespread availability of the HPV vaccine. Most proponents of vaccination programs emphasize the continued need for screening, but there has been speculation that screening could begin at an older age or be required less often than it is now if the majority of the population has been vaccinated (12).

**Safety of the HPV Vaccine**

The most comprehensive inquiry into the safety of the HPV vaccine to date was conducted by Slade et al and published in JAMA in August 2009 (18). Their study summarized reports made to the Vaccine Adverse Event Reporting System (VAERS) following receipt of the quadrivalent human papillomavirus recombinant vaccine (qHPV). When the study was conducted, more than 23 million doses of qHPV had been administered in the United States, as of December 2008 (18). This large sample size provides promise for accuracy, but the nature of the VAERS as a voluntary reporting system necessitates the consideration of the possibility of underreporting (18). Notably, VAERS data does not always convey a causal relationship between the vaccination and the adverse event (18). It does, however, provide useful insight into potential side effects of vaccination. The study’s results are as follows:
“VAERS received 12,424 reports of adverse events following immunization (AEFIs) following qHPV distribution, a rate of 53.9 reports per 100,000 doses distributed. A total of 772 reports (6.2% of all reports) described serious AEFIs, including 32 reports of death*... The most frequent serious symptoms included 159 reports of headache (21%), 119 nausea (16%), 113 dizziness (15%), 102 vomiting (13%), 102 pyrexia (13%), 102 fatigue (13%), and 98 syncope (13%). Medically important serious events included 8 reports of anaphylactic reaction (1%), 9 deep vein thrombosis (1.2%), 31 Guillain-Barre syndrome (4%), 25 hypersensitivity (2.5%), 10 transverse myelitis (1.3%), 6 pancreatitis (0.8%), 14 pulmonary embolism (1.8%), 23 death* (3%), 68 convulsion (8.8%), 30 urticaria (3.9%), and 9 autoimmune disorder (1.2%)” (12).

*“Reported deaths with available records, autopsy reports, or death certificates (20/23) describe causes other than recent vaccination” (18).

These findings demonstrate that the AEFI rates for HPV vaccination were similar to the background rates for other vaccines, with the exception that there was higher reporting of syncope and venous thromboembolic events (18). Of the reports received by VAERS, 93.8% were non-serious events (18). Slade et al compared their findings as reported to VAERS to the adverse events reported by clinical trials. In the clinical trials, incidence of AEFIs were similar for the placebo and vaccine groups (60% and 59%, respectively) (18). The rates of serious AEFIs were also similar between the placebo and vaccine groups (both less than 0.1%) (18). These data suggest that the safety risks
associated with the HPV vaccine are similar to other vaccines and are within the FDA recommended threshold (18).

Interestingly, Giuliano, Palefsky, and Goldstone et al reported lower rates of adverse events in their trial in comparison with clinical trials involving solely women (17). The most common adverse events reported by the boys and men in the Giuliano trial were an increase in oral temperature and injection site pain (17). In both the intent-to-treat and the per-protocol groups, approximately 14% reported vaccine-related systemic adverse events, none of which were classified as serious (17). The authors speculated that the lower rate of adverse events in their trial may be attributable to the males having more muscle mass at the injection site, feeling less inclined to report events perceived as minor, or both (17).

Cost of the HPV Vaccine

Gardasil is an expensive vaccine. It must be administered in 3 doses, with each dose costing $120, for a total of $360.00 (19). Following the ACIP recommendation of the HPV vaccine, “a federal contract for vaccine purchase was negotiated... Allowing states to purchase vaccine with public funds (either federal or state) at a reduced rate of $96/dose” for a total of $288 for the three doses required per recipient (20). All fifty states purchased HPV vaccine through this federal contract in 2007 for use in the Vaccines for Children (VFC) and State Children’s Health Insurance (SCHIP) programs, which provide vaccines to children who qualify for Medicaid, are uninsured, or underinsured (20, 21). Both VFC and SCHIP cover all ACIP recommended vaccines. Additionally, most private insurers cover ACIP recommended vaccines, although as of
2007, 12% of girls aged 9 to 18 were uninsured (21). The high cost of the HPV vaccine is partially due to the fact that it is the result of the recombinant DNA technology previously discussed that makes the vaccine both extremely effective and very safe. Although safety is unquestionably a good thing, it doesn’t change the fact that the vaccine is so expensive. From a legislative perspective, it is much more difficult to justify mandating an expensive than an inexpensive vaccine when resources are limited.

Quality adjusted life years (QALYs) are used in public health to make cost/benefit analyses of proposed public health interventions. A more expensive vaccine represents a higher cost per QALY gained. Whenever a cost/benefit analysis is to be performed for a prophylactic treatment, such as vaccination, the costs of protection from the disease must be weighed against the cost of managing and treating the disease in the absence of the protective measure, i.e. the cost of the HPV vaccine for many must be weighed against the cost of cervical cancer for a few. A QALY-based analysis comparing the cost of vaccination to the cost of treating HPV-associated cancers was done in Denmark in 2010 (22). The projected annual cost of vaccination was €9.4 million (a cost that must be added to the cost for screening), and the projected annual savings from vaccine-prevented cervical cancer treatments was €8.4 million (22). Vaccinating 70% of Denmark’s 12 year old girls was determined to be cost effective at the rate of €1,917 per QALY gained (22). The authors concluded that HPV vaccination of 12 year old girls in Denmark would present added cost but would be cost effective and “would save treatment costs and improve both quality of life and survival” (22). U.S.-based models have estimated that vaccinating healthy eleven and twelve year old girls will cost between approximately $30,000 and $43,000 per QALY gained (23). In comparison, screening for cervical
cancer with Pap smears every two years costs about $76,000 per QALY gained (24). However, vaccination will not preclude the need for Pap smears and thus vaccination costs are in addition to the cost of screening. Prophylactic public health measures are typically considered cost effective when they cost less than $50,000 per QALY gained, so by standard judgments, the HPV vaccine is cost effective when administered to eleven and twelve year old girls in the United States (25).

It is not yet known how much state mandated vaccination will cost, but over the next several years we will be able to gather data on cost from Virginia and the District of Columbia, the only two jurisdictions in the US that have mandated HPV vaccination for school-age girls. Both of these areas have extremely wide opt-out provisions for parents, so data on how many parents opt out of vaccinating their daughter will also provide useful insight into the cost of mandating the HPV vaccine. It is also not yet known for how long the vaccine confers immunity. If future research demonstrates that booster shots are necessary for extended immunity, then the vaccine will be less cost effective (26). It is not currently known whether or not Gardasil will be available as a cheaper generic, but certainly a less expensive option for achieving the same public health goals would be desirable.

The cost of Gardasil must also be considered in light of the cost of other childhood vaccinations: “In 1995, it cost $155 to give a child all the CDC-recommended vaccines; today, the cost has risen to $834, not including the HPV vaccine, according to CDC statistics” (19). Additionally, while most other childhood vaccines represent a cost-savings from a legislative perspective since they are so inexpensive and prevent so much medical care from infectious disease, the HPV vaccine does not represent cost-savings,
despite the fact that it is cost effective when administered to the recommended population (25). The only other vaccine that does not represent cost-savings that has been mandated is the meningococcal vaccine, which, like the HPV vaccine, is given to adolescents rather than young children (25). The cost of childhood vaccination puts financial strain on families, physicians, and health departments. Pediatrician’s offices and family practices must purchase vaccines up front and be reimbursed when patients receive them. In order to preserve our society’s ability to vaccinate children against childhood communicable diseases, the addition of an expensive vaccine like Gardasil to the list of mandated vaccines should be carefully considered.

Unfortunately, the FDA approval and release of Glaxo-Smith Kline’s HPV vaccine Cervarix has not yet created a competitive market; Merck has not lowered the cost of Gardasil, at least in the United States (25). Today’s society has acknowledged the rising cost of healthcare and no one would argue that preventive interventions should be mandated no matter their cost. Cost matters, and certainly if a mandate will put financial strain on states, that should be carefully weighed against the benefits of vaccination.

This chapter has sought to provide insight into the scientific basis for HPV vaccine mandates (the disease burden of HPV and cervical cancer), as well as information on the efficacy, safety, and cost of the HPV vaccine. This data is relevant because it would be immoral to mandate the HPV vaccine without demonstrating that it is safe and effective to a similar extent as other mandated vaccines. Affordability is another prescient legislative concern. The data presented herein will be analyzed to answer these questions later.
References, Chapter 2


Legislative Concerns

Legislators in all 50 US states have had to grapple with the issues surrounding the HPV vaccine. Forty one states dealt with proposed legislation within one year of the HPV vaccine’s approval. There are a number of issues these legislators have had to confront with the HPV vaccine, some of which are not unique to the HPV vaccine and some of which are. There are legal and legislative precedents for vaccine mandates and exemptions to them that are pertinent to all vaccine mandate legislation, though exemptions have been expanded specifically for the HPV vaccine in some states. There are a number of issues that are unique to this policy debate, however. These include the issues surrounding mandating protection against a sexually transmitted infection that can be prevented through abstinence, the special broad opt-out provisions provided by states mandating the vaccine, and the legislative pressure created by the vaccine manufacturer’s marketing campaign. I will analyze these issues in turn and then provide a summary of the HPV legislation that has been proposed and passed.

Legal Precedents for Vaccine Mandates

States have been mandating vaccines to protect the public’s health for more than a century (1). Court decisions at every level of federal and state jurisdiction have supported the right of the state to require vaccination (2). Landmark decisions regarding vaccine
mandates include *Jacobson v Massachusetts* (1905) and *Zucht v King* (1922). *Jacobson v Massachusetts* established the power of the state to implement vaccine mandates and override the autonomy of the individual in order to benefit the community. *Zucht v King* extended the *Jacobson* decision to give the state power to compel parents to have their children vaccinated in order to enter school.

On February 20, 1905, the US Supreme Court issued a landmark decision in *Jacobson v Massachusetts*: by a vote of 7 to 2 it concluded that the US Constitution does not guarantee a right to refuse vaccination (3). The *Jacobson* case centered around the case of Henning Jacobson, a Swedish immigrant and Lutheran minister living in Cambridge Massachusetts who refused to undergo free vaccination against smallpox due to his belief that God would protect him from the disease (3). In addition to refusing to be vaccinated, Jacobson also refused to pay the $5 fee for vaccine refusal charged by the city of Boston. He was tried in county district court and found guilty, so Jacobson appealed to the county superior court, which affirmed the lower court’s verdict. Jacobson then took his case to the state supreme court, where his lawyer argued that compelling Jacobson to undergo vaccination against his will was a violation of his religious beliefs (3). The state supreme court decided against him and so Jacobson took his case to the US Supreme Court, where Jacobson’s lawyer argued that compulsory vaccination was a violation of the Fourteenth Amendment, which “forbids states from denying any person ‘life, liberty or property, without due process of law’” (4). After debating for almost two years (the case had been added to the docket on June 29, 1903), the court decided that states have a right to compel citizens to undergo vaccination. They concluded that states’ “legal authority to require immunization rests on states’ 10th amendment ‘police powers,’
the inherent authority of a government to impose restrictions on private rights for the sake of public welfare, order, and security” (2, 3). The constitutionality of police powers is based on evidence of four criteria: first, “there must be a public health necessity,” second, “there must be a reasonable relationship between the intervention and public health objective,” third, “the intervention must not be arbitrary or oppressive,” and four, “the intervention should not pose a health risk to its subject” (5). In chapter five, I will use theJacobson court’s criteria of a public health necessity to demonstrate that HPV should not be mandated for public schools in the United States. Since Jacobson, states have mandated many vaccines based on police powers. TheJacobson decision has ramifications that extend far into the realm of public health; the court determined that “real liberty for all could not exist under the operation of a principle which recognizes that the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others” (2). Jacobson v Massachusetts established the power of the state to implement vaccine mandates and override the autonomy of the individual in order to benefit the community, essentially supporting Mill’s harm principle, which advocates each citizen’s exercising of his or her own rights insofar as he or she does not infringe upon the rights of others or cause harm to others (6).

Since Jacobson v Massachusetts, many public health interventions have been undertaken with the nation’s public schools serving as an enforcement mechanism. School mandates have become the customary means of enforcing vaccine mandates by “converting recommendations for new vaccines into legally enforceable obligations. Over time, school mandates have created the impetus for increased coverage rates among
all children, have decreased the incidence of infectious disease, and have reduced racial and ethnic disparities among school-age children” (2). The role of public schools as an enforcement mechanism for vaccine mandates was challenged in 1922 when the Supreme Court decided Zucht v King. A Texas ordinance required all school children to present a certificate of vaccination in order to enroll, and when the Zucht family refused to have their fifteen year old daughter Rosalyn vaccinated, her high school expelled her. Rosalyn’s parents sought legal recognition of their refusal to vaccinate their daughter, claiming that her expulsion violated her constitutional rights, but the Court established that “states may require parents to have their children vaccinated in order to promote the best interests of the broader community” (2). Zucht v King extended the Jacobson decision to give the state power to compel parents to have their children vaccinated in order to enter school. Zucht v King was also a landmark decision because Texas was not in the midst of an epidemic in 1922 the way Massachusetts had been when Jacobson was decided. Another important result of Zucht v King was the legal distinction between compulsory vaccination (Jacobson) “in which people who refuse are forcibly vaccinated” and mandatory vaccination (Zucht v King) “in which people who refuse are denied social privileges, like attending public school” (3). Mandatory vaccination has been upheld in US courts as more defensible than compulsory vaccination since mandatory vaccination gives the citizen a choice: get the vaccine, or lose a social privilege. However, when the social privilege lost is attendance at public school, the stakes are so high that one must consider whether a parent (especially a parent of limited means) actually has a practical choice in the matter. It is a testament to the importance of vaccines in protecting the
public’s health that the US Supreme Court decided that it was constitutional to impose such a mandate.

*Jacobson v Massachusetts* (1905) and *Zucht v King* (1922) set legislative precedents for states to mandate vaccines as school-entry requirements based on the states’ police powers. For each vaccine, an analysis of whether or not the criteria necessary for a state to use its police powers is met must be made. In chapter five, I will argue that the HPV vaccine does not justify the use of state police powers since HPV does not constitute a public health necessity.

**Exemptions to Vaccine Mandates**

Exemptions from vaccine mandates represent the state’s effort to balance parental autonomy and public health; “states attempt to strike some balance between the power to require vaccination and consideration for parental beliefs and autonomy by allowing for exemptions from vaccine requirements” (7). Exemptions to vaccine mandates take one of three forms: they are medical, religious, or philosophical. As of 2011, all fifty US states allow exemptions to vaccine mandates for medical contraindication (8). These often are provided due to an allergy to a component of a vaccine or due to ongoing medical treatment that would adversely interact with vaccination, such as chemotherapy. Forty eight US states (all except West Virginia and Mississippi) allow exemptions to vaccine mandates for religious reasons, though states vary as to what is required to qualify for a religious exemption claim (9). Twenty states allow exemptions to vaccine mandates for philosophical reasons, which allow one to qualify for exemption if he or she disagrees with the practice of vaccination based on personally held beliefs (9).
The story of vaccine mandate exemptions is a fascinating one that highlights the power of legal precedent and lobbying efforts. The legal precedents for state mandated vaccination set by *Jacobson v Massachusetts* (1905) and *Zucht v King* (1922) were followed by a flurry of cases that eventually resulted in religious exemption clauses in every state, though two states later redacted their religious exemption clauses from the state vaccine mandate legislation. Interestingly enough, the first precedent for vaccine mandate exemptions was against, not in favor of, religious exemption and was based on a case that had nothing to do with vaccines, but instead focused on child labor laws (3). The case was *Prince v. Massachusetts* (1944) and centered on a Jehovah’s Witness who took young children with her to pass out pamphlets even though she was aware that the children’s involvement in her evening work violated child labor laws. The court’s conclusions in *Prince* extended beyond child labor laws, with the majority opinion stating, “The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death. Parents may be free to become martyrs themselves, but it does not follow that they are free, in identical circumstances, to make martyrs of their children” (3). The precedent set by *Prince v. Massachusetts* is that religious exemptions from vaccine mandates are not appropriate, and this was upheld for decades: case after case in the 1960’s, 1970’s, and 1980’s found that it was not a violation of religious freedom to compel parents to vaccinate their children to enter school since the vaccine mandates applied to all people, regardless of religion (3). All this changed when Christian Scientists successfully lobbied the state legislature in New York to allow them exemption from vaccine mandates since they believed that prayer prevented and healed diseases. Once an exemption was allowed
for one religious group, courts found it unconstitutional to allow vaccine exemptions for one religious group but not others and “by 2009, forty-eight states allowed religious exemptions to vaccination” (3).

Once religious exemptions had been well-established, parents began seeking exemptions based on other beliefs, and one judge found that “vaccine exemptions could be granted if ‘beliefs were held with the strength of religious conviction,’ even if parents weren’t members of a religious group” (3). Exemptions offered on these grounds became what are today called philosophical exemptions, which twenty two states currently allow. Many refer to philosophical exemptions as catch all waivers since they typically do not require a strict burden of proof of strongly held beliefs and because more and more parents are seeking them: “between 1991 and 2004, the number of unvaccinated children in states with philosophical exemptions more than doubled” increasing from 0.99 to 2.54% (3, 10, 11). The ramifications of lower vaccination rates will be discussed in chapter four.

Exemptions to vaccine mandates are relevant to the legislative debate over mandating the HPV vaccine because these exemptions have been expanded specifically for the HPV vaccine in Virginia and the District of Columbia, the two jurisdictions to have passed school mandates for the vaccine. These laws allow parents to choose to opt-out of the HPV vaccine “for any reason,” a broader exemption than has been allowed for any vaccine in US history (8). The DC and Virginia laws included this broad opt-out provision since HPV is sexually transmitted (8).
Mode of Transmission Matters: Mandating Vaccination for an STI

Much of the debate surrounding the HPV vaccine has stemmed from the nature of HPV as an STI. People have a “sense that this vaccine is different from previously mandated vaccines because it attempts to prevent disease whose sole route of transmission is through sexual contact” (12). It is significant that HPV is only spread through sex because this means that HPV is not casually communicable, meaning it cannot be spread through every-day contact like breathing the same air or shaking the hand of an infected person. All previously mandated vaccines protect against casually communicable diseases, with the exception of Hepatitis B, which will be discussed shortly.

Some opponents of a school-based HPV vaccine mandate claim that providing vaccination against an STI will encourage promiscuity in girls that otherwise would have been chaste (13). Conservative groups have expressed concern that providing the vaccine to young girls will “undermine family values forbidding pre-marital sex” and give young girls and women a false sense of security regarding sex (13). In summary, some “opposition seems to be based on the concern that to recognize the reality of teenage sexual activity is implicitly to endorse it… some critics argue that the availability of a simple and safe alternative- that is, abstinence- undermines the argument for a state initiative that encourages vaccination through mandates coupled with an option for parental refusal” (1). The problem is that abstinence is not a simple alternative. Multiple factors contribute to the age at which girls begin having sex. 25% of American youths have had sex by age 15, 48% have had sex by age 17, and by age 19, this percentage jumps to 70% (1, 2). HPV infection rates as high as 40% have been identified in young
women with only one sexual partner (1). Additionally, abstinence-only programs have been shown to have no significant impact on adolescent sexual behavior (1). Sex-education programs, including the distribution of condoms, have not increased sexual activity among adolescents (1). In fact, sex-education has been shown to “delay initiation of sexual intercourse, reduce frequency of sex, reduce frequency of unprotected sex, and reduce the number of sexual partners” (1). Research has also shown that fear of contracting an STI is not a large factor in abstinence, so it is unlikely that perceived protection from STIs will result in earlier sexual debut (14). This evidence demonstrates young girls are not likely to remain abstinent (and thus HPV free) and that educating them about sex, including education about Gardasil, may actually decrease their sexual activity and increase the likelihood that they will practice safer sex. It is extremely difficult to differentiate between adolescent girls at high risk for contracting HPV from those at lower risk due to the private nature of sexuality. Due to the high prevalence of HPV among girls with one or more sexual partners and the inability to define and target high-risk groups, “widespread rather than targeted immunization of young women will provide a greater public health benefit against this ubiquitous infection” (15). This provides a compelling argument for state-funded programs designed to increase HPV vaccine uptake, whether they be insurance mandates or educational programs. The fact that some opponents of school-based HPV vaccine mandates base their opposition on misconceptions of adolescent sexuality should not be misconstrued as evidence in favor of school-based mandates. Rather, this simply demonstrates that not all opponents of HPV vaccine mandates have similar reasons for opposition and that some reasons are more valid than others. School-based HPV vaccine mandates are not likely to encourage
promiscuity in adolescent girls, and that should not be a concern of legislators considering a mandate.

Building on the quandaries presented by the nature of HPV as an STI, another argument regarding the inappropriateness of an HPV vaccine mandate is the role of the public school as the enforcement mechanism of a mandate. Since adolescents presumably will not be giving one another HPV in the classroom or at school, why should young girls have to be vaccinated in order to attend? Those who oppose a mandate on these grounds feel that “the purpose of vaccination mandates is to prevent the spread of contagious disease in schools, not to use school attendance as a lever to achieve other public health goals” (16). In 2000, the Arkansas Supreme Court upheld the constitutionality of mandating vaccination in schools against infectious diseases that are not casually communicable in *Boone v Boozman* (8). Mrs. Boone did not want her daughter, Ashley, vaccinated against Hepatitis B, a sexually transmitted virus that can cause liver damage and cancer. When Ashley was not admitted to school due to failure to demonstrate proof of vaccination, Mrs. Boone applied for a religious exemption and was denied on the grounds that her reasons for refusing the vaccine for her daughter were not ascribable to a recognized church or religious denomination (8). Though the court repealed the portion of the state’s exemption clause that required a parent to be affiliated with a recognized church in order to qualify for exemption, Ashley was required to be vaccinated against Hepatitis B in order to enroll in public school, and the court found such a mandate constitutional (8).

Many parents made the same arguments about Hepatitis B vaccination that are being made today about HPV vaccination. They argued that the sexually transmitted
nature of the disease made it inappropriate to require the vaccine for school attendance. The parents further argued that Hepatitis B did not present a clear and present danger since it could be avoided through abstinence. The Boone court determined that a disease doesn’t have to be casually communicable in order to present a clear and present danger, citing the ability of the Hepatitis B virus to remain viable on inanimate surfaces such as doorknobs (8). (It is not known whether or not or for how long Hepatitis B or HPV actually survive outside the body. The Supreme Court seemed to think that even though Hepatitis B is primarily sexually transmitted that casual contact with infected individuals may increase one’s chances of transmission, similar to concerns regarding casual contact with HIV positive individuals.) The court determined that “requiring school children to be immunized against Hepatitis B is a reasonable exercise of the State’s police power and is constitutionally permissible” (2). The Boone decision set a precedent that requiring vaccination against an STI as a prerequisite to school entry is constitutional and appropriate even when the infection is not casually communicable. At least forty-two states currently require children to receive Hepatitis B vaccine as a precondition for school enrollment (8).

The primary difference between Hepatitis B and HPV is a significant one that is often overlooked in the literature: Hepatitis B can kill children on its own, long before liver cancer ever develops (17). It is a devastating infection in very young children, and the chance that an infected person will become a life-long sufferer of chronic hepatitis decreases with age, meaning that young children are at highest risk of developing life-long complications from infection. In very young children, approximately 90% of those infected develop chronic hepatitis, while in adults, only about 10% have life-long
complications (17). HPV, while far more common than Hepatitis B, is a far less harmful virus. Most HPV infections clear on their own, and many people never know they’ve been infected. The most serious HPV infections are those that newborn infants acquire from their mothers during birth, which can be quite harmful, but obviously occur long before the child enters school (17). HPV and Hepatitis B are similar only in their mode of transmission, i.e. through sexual contact or contact with bodily fluids or maternal-fetal transmission in birth, and also in their propensity to cause cancer decades down the road. It is significant, however, that if a child catches Hepatitis B, their health may be in imminent danger, but if a child catches HPV, they are not in imminent danger from the virus itself. This simple biological fact illustrates a logical flaw in the reasoning that if states have mandated Hepatitis B vaccine, it follows that they can mandate HPV vaccine for the same reasons. Thus, while Boone v. Boozman provides a precedent that states may mandate the Hepatitis B vaccine for school children, further consideration should be given to the imminent danger presented by each disease individually (17). Since Hepatitis B is imminently dangerous and HPV is not, HPV should not be mandated for public school children despite the fact that HPV and Hepatitis B are similarly transmitted through sexual contact.

*Merck’s Marketing Campaign Created Legislative Pressure*

A final piece of the puzzle that legislators must put together when considering a mandate for the HPV vaccine is the marketing campaign Merck launched for the Gardasil vaccine and its repercussions in the political arena. Merck, the pharmaceutical giant that manufactures Gardasil, launched an extensive ad campaign that included television
commercials and magazine and internet ads, all of which were aimed at the general public. Merck marketed the vaccine not as a vaccine that conferred immunity against the human papilloma virus, but as a vaccine that conferred immunity against cervical cancer. This marketing strategy allowed them to minimize the potentially controversial sexually transmitted nature of HPV, focusing instead on the loftier goal of preventing cancer (18). Merck’s marketing was incredibly misleading and largely missed the point of the HPV vaccine. The marketing campaign not only misrepresented the biological functioning of the vaccine (i.e. it protects against a virus that can cause cancer, not against the cancer itself), but also the incidence of cervical cancer in the American population. The campaign slogan, “One Less” implied that each young woman had the same risk of developing cervical cancer, thereby ignoring the discrepancies in ethnicity and socio-economic class that have a strong bearing on a woman’s likelihood to develop cervical cancer (18). This strategy benefited the manufacturer by increasing perceived need for the vaccine but was “neither cost effective nor equitable” (18). Additionally, Merck’s advertising of Gardasil makes it seem as though once you have been vaccinated, your risk of developing cervical cancer is zero, which is inaccurate since other strains of HPV that the vaccine does not protect against can also cause cervical cancer (18). One medical school faculty member said, “I’m concerned that people believe that they are impervious to cervical cancer [after being vaccinated] because that’s what the ads and TV and media have been saying” (19). In order to counter-act the misleading marketing of the HPV vaccine, educational efforts are needed to ensure that young girls and women who receive the vaccine understand that it does not protect against all STIs, or even all strains of HPV, and that women still need routine Pap smears to screen for cervical cancer.
interview, Jon Abramson indicated that public misperception will likely not have a negative impact on Pap screening, saying “It’s a misconception that women who would otherwise get a Pap smear are now not going to because they’re vaccinated. I think the benefit of getting the vaccine far outweighs the risk that women won’t show up for their Pap smear” since OB-Gyns and family practitioners still recognize the continued need for Pap smear cervical cancer screening and since the public is largely unaware of the basis for Pap smears anyway (17).

In a JAMA article published in 2009, Sheila and David Rothman revealed that in addition to misleading the public, Merck provided funding to well-established professional medical associations, including the American College of Obstetricians and Gynecologists (ACOG) and the American Society for Colposcopy and Cervical Pathology (ASCCP). The ASCCP formed an “Educate the Educators” program designed to educate physician and lay audiences on the benefits of HPV vaccination (18). The “Educate the Educators” program, unfortunately, did much to misinform and manipulate those who attended. Participants were instructed to “help in convincing states and federal agencies to pay for the vaccine, convincing insurance to pay for it, and encouraging state mandates for use” and “downplay the sexually transmitted infection issues surrounding HPV” (18). The educational materials “omitted cautionary qualifications” and “did not include data on disparities in cervical cancer incidence and outcomes” (18). The most potentially harmful educational material was aimed at college students, telling them not to worry about cervical cancer anymore, thereby laying the ground-work for a generation of young women who think they don’t need Pap tests if they get vaccinated (18). Rothman laments, “pharmaceutical company campaigns can undercut the most cost-
effective and appropriate use of new agents to the detriment of adolescent health. By making this vaccine’s target disease cervical cancer, the sexual transmission of HPV was minimized, the threat of cervical cancer to all adolescents maximized, and the subpopulations most at risk practically ignored” (18). The “Educate the Educators” program that the ASCCP formed with Merck funding and Merck oversight did much to miseducate many in the health care industry, and grossly overstated the benefits and downplayed the burdens of Gardasil to the average American woman.

Professional medical associations were not the only ones to receive Merck funding. Women in Government, a national organization of female legislators in the upper echelons of American government, has been one of the most effective advocates for mandating the HPV vaccine. Women in Government has issued recommendations that all 50 states “add (Gardasil) to their Medicaid programs and encourage private health plans to cover it” (20). Merck, the manufacturer of the Gardasil vaccine, “provided unrestricted funds to Women in Government… Many of the bills to require HPV vaccination were introduced by Women in Government members” (16). Obviously, Women in Government has an unacceptable organizational conflict of interest. This provides evidence for serious concern regarding the proposals made by Women in Government members. However, not all proposed mandates were made by Women in Government legislators, and certainly the national conversation about mandating the HPV vaccine has not consisted exclusively of these women advocating the vaccine and all others opposing implementation of a mandate. So while this fact reveals inappropriate conflicts of interest in key legislative players, it does not justify an end to the debate or a conclusion that all policy-makers in favor of a mandate have inappropriate motivations.
The fact that corruption exists does not mean that meaningful, principled arguments may not be made.

Merck canceled its nationwide lobbying efforts in February 2007 out of fear that its aggressive lobbying may hinder vaccine acceptance (15). The reluctance of some state legislatures to pass proposed HPV vaccine mandates may be related to Merck’s aggressive lobbying efforts and the public outcry it has produced (21). Thanks to Merck’s marketing campaign, some legislators may overestimate the benefits and underestimate the burdens of the HPV vaccine, which is detrimental to the policy-making process.

**HPV Vaccine Legislation**

Table 1 (pages 54-56) provides a summary of the legislation that has been passed related to the HPV vaccine.

Within only one year of the FDA approval and subsequent ACIP recommendation of the HPV vaccine, forty-one states proposed measures related to increasing uptake of the HPV vaccine (16). Twenty-four of those forty-one states proposed mandating the HPV vaccine for girls entering public schools. Notably, the California proposal was transformed into an insurance coverage mandate and passed, but was vetoed by the governor. Similarly, the New Mexico proposal was also passed, but was also vetoed by the governor (16). In 2007, Texas, which has the second highest prevalence of cervical cancer in the United States, became the first state to mandate that girls receive the HPV vaccine prior to entering sixth grade when Governor Rick Perry signed an executive order mandating the vaccine, thereby circumventing the state legislature (5, 16). Perry’s
actions created a public outcry, with parents and state legislators claiming, “providing the vaccine was giving tacit approval to premarital sex, when Texas endorses a program of abstinence until marriage in school sex education courses” (22). It was also revealed that Merck had donated a substantial sum of money to Perry’s political campaign. The Texas state legislature repealed the executive order a few months later.

As of 2011, only Virginia and the District of Columbia have passed and signed into law mandates requiring HPV vaccine as a prerequisite to school entry (5, 8, 16). In 2008, the Virginia General Assembly passed a bill mandating that girls receive the HPV vaccine prior to entering sixth grade. An extremely liberal opt-out provision recommended by the governor was added that allows parents to refuse the vaccine for their daughter “because the human papillomavirus is not communicable in a school setting” (8). Notably, parents must review “materials describing the link between the human papillomavirus and cervical cancer” before they may opt-out (8, 23). The DC law requires girls to receive the HPV vaccine before entering sixth grade and allows parents to opt-out “for any reason” (8). These ‘catchall waivers’ found in the Virginia and DC mandates attempt to respect parental autonomy, which is lacking from mandates with less expansive exemptions, but broad opt-outs may also pave the way for broader opt-out provisions to other vaccine mandates, which could potentially endanger the public health, which is a serious concern.

New Hampshire successfully implemented legislation involving the HPV vaccine, but took a far different approach from mandates. Instead of requiring the vaccine for girls to enter school, the state has committed to providing the vaccine free of charge to all girls between eleven and eighteen years of age, and has experienced vaccine shortages
across the state, indicating that cost of the vaccine may be a primary obstacle in vaccine uptake (5). In addition to the laws passed in Virginia, DC, and New Hampshire, eight states have enacted laws requiring insurance companies to cover the vaccine or allocating state funds to provide it. Additionally, eight states have enacted laws designed to promote education and awareness, and three states have formed committees to examine the issue further (23).

Colgrove et al published a study in the *New England Journal of Medicine* in which they interviewed 73 key informants in six states in order to determine what factors had been most “influential in determining how states acted on the issue of mandates” (16). They found that those in favor of mandates were most persuaded by the “severity of cervical cancer and the efficacy of the vaccine,” as well as the nature of mandates in increasing equity in vaccine uptake. Colgrove et al also found that eight factors hindered adoption of school mandates: the newness of the vaccine, the sexually transmitted nature of HPV, the non-transmissibility of HPV in the classroom setting, discomfort with the vaccine manufacturer’s involvement, the price of the vaccine, antipathy toward governmental coercion, anti-vaccination activism, and the nature of the policymaking process (16). Each of these factors is discussed in this thesis, and the consistency of these factors across the literature highlight the uniqueness of the policy decisions regarding HPV vaccine.
**TABLE 1: State Exemptions and Legislation on the HPV Vaccine**

**KEY:**
- “Insurance Mandate” indicates that the state passed legislation either requiring insurance companies to cover the cost of the vaccine or they allocated state funds to cover the cost of the vaccine.
- “Education” indicates that the state passed legislation intended to promote awareness of the HPV vaccine through educational efforts.
- “Expert Body” indicates that the state passed legislation to form an expert body to further investigate the issue of mandating the vaccine.

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<th>Philosophical Exemption</th>
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Table 1 data is from the CDC, Offit (3), the NCSL (9), and Javitt et al (23).
References, Chapter 3


CHAPTER FOUR

OPPOSITION TO VACCINES, THE ROLE OF PARENTS AND PEDIATRICIANS, AND IMPLICATIONS FOR HPV VACCINE

The Anti-Vaccine Movement

The debates surrounding the HPV vaccine must be understood in the context of a larger debate going on in American society. This larger debate is about the safety and efficacy of childhood vaccines in general, and though it is a multi-faceted movement involving many people with a wide range of beliefs, the most extreme anti-vaccine activists have produced the most media coverage thanks to their concerted efforts and have affected millions of parents’ decision-making processes about whether or not to vaccinate their children. Paul Offit, M.D., chief of the Division of Infectious Diseases and the director of the Vaccine Education Center at the Children’s Hospital of Philadelphia, characterizes the anti-vaccine movement as a “quiet, deadly war,” with those who believe vaccines are dangerous and cause chronic diseases on one side, the scientific community producing evidence against their claims on the other side, and confused parents and vulnerable children caught in the middle (1). One must understand the anti-vaccine movement to understand some of the opposition to mandating the HPV vaccine, but there are certainly many who are not anti-vaccine yet are opposed to a mandate for the HPV vaccine; their arguments will be analyzed in chapter 5.

There is no doubt that the United States has a substantial and growing anti-vaccine culture, a movement that is furthered by publicity provided by celebrities, elected officials, and some parents. While national vaccination rates have remained relatively
high, there are pockets of communities within the United States where vaccination rates have dropped dangerously low, creating populations that are extremely susceptible to infectious disease (2, 3). The result is that infectious diseases like measles, Haemophilus influenzae type b (Hib, which causes bacterial meningitis), pertussis (whooping cough), and mumps are coming back.

This is relevant to discussions involving a mandate for the HPV vaccine for several reasons. First, immunizations against potentially fatal, casually communicable infectious diseases should take priority over a prophylactic vaccine like the HPV vaccine. If states are having trouble maintaining herd immunity against more serious infectious diseases, their resources should not be diverted to mandating the HPV vaccine. Second, it is a concern that mandating the HPV vaccine may strengthen the anti-vaccine movement by encouraging opposition among parents. Since it is a controversial vaccine due to the nature of HPV as an STI and the fact that HPV does not pose imminent risk of danger to school children, parents may feel compelled to oppose all vaccines if their daughter is required to get this one controversial vaccine. Third, in the jurisdictions where HPV vaccine has been mandated, extremely broad opt-out provisions have been incorporated into the law allowing parents to opt-out of the HPV vaccine for any reason. This may open the door for broader opt-out provisions in other vaccine mandates, which would endanger public health. It is a concern that if such broad opt-outs were to seep into other vaccine mandate legislation, it would be easier for parents to refuse potentially life-saving vaccines for their children and encourage a public perception that childhood vaccines are not that important.
Unvaccinated Children are a Threat to Public Health

Measles is one of the most infectious diseases on earth. In 2008, a measles outbreak started with one unvaccinated boy in California who got measles when he traveled to Switzerland, where vaccination rates are lower and infection rates are higher than in the US (1). This one case of measles started an outbreak that spread to thirteen other states, infecting one hundred and forty children and hospitalizing twenty, all of whom had not received the vaccine (1). Measles continues to cause outbreaks in other countries and ever year about sixty people with measles enter the United States from other countries (1). The difference between 2008 and prior years when measles has been brought into the country was that in 2008, there was a susceptible population of unvaccinated children who contracted the disease, causing an outbreak. A similar measles outbreak occurred three years earlier, in 2005, when a little girl from Indiana visited Romania on a mission trip and contracted measles in an orphanage. When she returned home, she attended a church picnic with about 500 other people, 35 of whom had never been vaccinated against measles (1). 89% (31) of the picnic attendees who had not been vaccinated against measles contracted the disease that day (1). Only 0.6% (3 cases) of the picnic attendees who had been vaccinated contracted measles (1). The measles virus successfully infected almost every susceptible person at that picnic. The same can happen in any public place.

Measles is not the only infectious disease that is coming back thanks to lower vaccination rates. Table 3 on page 77 provides a summary of the outbreaks that have occurred in the US in the last five years. Outbreaks of Hib occurred in 2008-2009 in five states, infecting several unvaccinated children and killing five unvaccinated children (1).
Before the Hib vaccine, this bacteria infected and caused “meningitis, bloodstream infections, and pneumonia in twenty thousand children every year, killing a thousand and leaving many with permanent brain damage” (1). Pertussis outbreaks have occurred in eight states in the last five years (1). Before the vaccine was created in the 1940s, there were about three hundred thousand cases and seven thousand deaths from pertussis, or whooping cough, each year (1). In 2006, mumps infected 6,500 people, mostly college students, across the midwest. In New York in 2009, fifteen hundred Hasidic Jews were infected with mumps after an eleven-year-old boy got the virus on a trip to England, where vaccination rates were low and infection rates were high (1).

Despite these outbreaks, national immunization rates remain high. The data in table 2 on page 76 demonstrate that while national vaccine coverage rates, as reported by the CDC according to the annual national immunization survey (a self-reporting measurement), remain above or just below levels required for herd immunity, the growing anti-vaccine movement poses risks to children whose parents refuse to vaccinate their children, as well as to those children who cannot be vaccinated due to a contra-indication such as a medical condition, an allergy, or an immuno-compromised state due to chemotherapy or other treatments (2). Susceptible communities also pose a risk to other members of the community since no vaccine is one hundred percent effective (1).

State-based vaccine mandates have traditionally protected herd immunity by ensuring that children receive vaccines before attending school (3). As indicated in chapter 3, all 50 states provide exemptions from vaccine mandates for those who have a health contra-indication and 48 states provide exemptions for those who cite religious opposition to the practice of vaccination (4). A growing number of states, 22 as of 2011,
also allow for philosophical exemptions, which allow one to qualify for exemption if he or she disagrees with the practice of vaccination based on personally held beliefs (4). The requirements for exemptions vary by state— in some places, quite a bit of effort is required to obtain exemption, while in others, a parent must simply fill out a readily available form (5).

**A Brief History of the Anti-Vaccine Movement in America**

Opposition to childhood vaccines has become so widespread and organized that it has been defined as a movement for the last two decades. The anti-vaccine movement is based on the idea that vaccines pose a greater danger to children than the diseases the vaccines protect against. Paul Offit provides a thorough examination of the anti-vaccine movement in America in his 2011 book, “Deadly Choices: How the Anti-Vaccine Movement Threatens Us All.” Offit examines how cultural events have changed the way parents view vaccines and why vaccination rates are dropping in communities throughout the US (1).

In 1982, a local news affiliate in Washington, DC aired a program that would provide the impetus for what became the anti-vaccine movement in America, sparking billions of dollars in litigation, driving changes in pharmaceutical manufacturing, and ultimately leading to the creation of a new federal program. The television program was called “DTP: Vaccine Roulette” (1). It was a sensationalized program that drew the public’s attention to the alleged potential risks associated with the Pertussis vaccine, a portion of the DTaP vaccine, which contains vaccines against diphtheria, tetanus, and pertussis (1). The program claimed that children suffered from seizures, irreversible
brain damage, and subsequent mental retardation and developmental delays as a result of receiving the DTaP vaccine and featured detailed anecdotal stories about children who suffered these symptoms (1). The “Vaccine Roulette” story evoked a public outcry that resulted in litigation and legislation reform. Pharmaceutical companies awarded billions of dollars to parents of children who had suffered symptoms that the program claimed were caused by vaccines (1). As a result, pharmaceutical companies more than doubled the price of the vaccine and could not afford to continue producing it under the crippling litigation claims (1). As a result, every single American pharmaceutical company that had manufactured and distributed DTaP vaccine prior to 1982 had ceased their production of the vaccine by 1986 (1). Not surprisingly, a vaccine shortage ensued. The vaccine shortage combined with parental refusal of the vaccine resulted in an exponential increase in pertussis cases among American children (1). Finally, the federal government created the National Childhood Vaccine Injury Act in late 1986, an Act that created a federal compensation program operated through a vaccine court that heard claims from parents whose children were adversely affected by vaccines and compensated them (1). This allowed American pharmaceutical companies to resume production of the DTaP vaccine and ended the vaccine shortage that had crippled American pediatrician offices (1). The medical and scientific communities have since established that the purported link between the pertussis vaccine and seizures, brain damage, and permanent retardation is false, but twenty-eight years’ worth of scientific investigation producing a literature boasting dozens of peer-reviewed controlled studies evaluating hundreds of thousands of children have failed to produce the public outcry that one television program prompted (1).
The DTaP vaccine debacle was largely a problem of faulty logic: the failure to recognize that a temporal association is not evidence of a causal association. In 2006, an Australian researcher published evidence that a genetic form of epilepsy was the true cause of the thought-to-be pertussis vaccine brain-damaged children (1). This form of epilepsy has an onset in the first year of life that is relatively close to when the DTaP vaccine was given. The number of children who suffered the damage of the genetic epilepsy after receiving the DTaP vaccine was the same number one would expect from statistical chance: the pertussis vaccine was a temporal coincidence, not a causal event. But good evidence doesn’t make good news: “not a single newspaper, magazine, or radio or television program carried the story” of the discovered cause of the pertussis debacle (1). Another prominent belief among vaccine opponents related to DTaP is that this vaccine causes sudden infant death syndrome (SIDS) (6). This belief became prevalent because most infants who die of SIDS die in the age range that the DTaP vaccine is given, but the fallacy of the logic is, once again, that a temporal association does not indicate a causal relationship (6). The CDC has reported that the number of SIDS deaths that are temporally associated with the DTaP vaccine is “within the range expected to occur by chance... In other words, the SIDS deaths would have occurred even if no vaccinations had been given… children who had recently gotten a DTaP shot were less likely to get SIDS” (6).

Unfortunately, the DTaP vaccine is not the only recommended childhood vaccine that has suffered the fate of adverse, sensationalized media coverage resulting in parents refusing to allow their children to be vaccinated. The measles, mumps, rubella (MMR) vaccine has been similarly attacked by false claims that the scientific community has
continually abrogated (1). It all began in 1998 when the *Lancet* published a paper by Dr. Andrew Wakefield, an English surgeon, reporting that eight children Dr. Wakefield studied had developed autism after receiving the MMR vaccine due to the presence of viral DNA in the cerebra-spinal fluid (1). Worldwide panic ensued and parents across the Western World chose not to vaccinate their children; measles outbreaks followed. In response to the worldwide panic, “twelve separate groups of researchers working in several different countries examined hundreds of thousands of children who had or hadn’t received MMR. The risk of autism was the same in both groups” (1). The scientific community was thus convinced that Dr. Wakefield’s hypothesis lacked evidence and that the MMR vaccine was safe and unconnected to autism. The story wasn’t over yet, though. Incriminating information was soon to be revealed: Wakefield had been paid about $800,000 to conduct the study by a personal injury lawyer representing five families whose children Wakefield had studied (1). After this was revealed, Wakefield’s co-authors withdrew their names from the study and one co-author revealed that he knew Wakefield had fabricated some of the evidence in the paper (1). In 2010, the *Lancet* officially retracted the paper, Wakefield lost his license to practice medicine in the United Kingdom, and the British Medical Journal called the paper “an elaborate fraud” (1).

Wakefield wasn’t the only scientist worried that vaccines might be causing autism: in 1999, the CDC and the AAP called for American pharmaceutical companies to stop using thimerosal, a mercury-containing compound commonly used as an adjuvant in vaccines. Their concerns were related to Wakefield’s study but hypothesized that it was not viral DNA in the cerebra-spinal fluid, but thimerosal, that was causing autism (1). However, “six large epidemiological studies examining the risk of autism in children who
had or hadn’t received vaccines containing thimerosal” were conducted soon thereafter and it was found that children who had received vaccines with thimerosal in them were not at any greater risk of developing autism than those who hadn’t (1). Despite the evidence, thimerosal was removed from American vaccines in 2001 (1). The removal of thimerosal from American vaccines had no impact on autism in American children and the prevalence of autism increased (1).

Frustrated parents started taking their autistic children to the vaccine court that was established as part of the National Childhood Vaccine Injury Act of 1986 and requesting compensation, claiming their children had developed autism after receiving the MMR vaccine. So many parents filed claims in vaccine court that the court set aside all else and dedicated two years to what became the Omnibus Autism Proceeding, which evaluated two theories (1). The first was that MMR and thimerosal caused autism, the second that thimerosal alone caused autism (1). In 2009, the special masters, or highest judges, of the vaccine court issued a verdict on the first theory: they would not compensate parents claiming that their child developed autism as a result of receiving the MMR vaccine. The special masters of vaccine court called the evidence of a link between the MMR vaccine and autism “weak, contradictory, and unpersuasive... when considering the impressive body of epidemiological evidence contradicting” the theory (1, 3). In 2010, the special masters of vaccine court issued a verdict on the second theory: they would not compensate parents claiming that their child developed autism as a result of receiving a thimerosal-containing vaccine, calling the evidence “scientifically unsupportable” (1, 3). These verdicts meant that over five thousand parents who had
claimed that their child had developed autism because of vaccines had to face the incontroversible fact that the scientific evidence did not support their belief.

However, scientific reason has had little success in overcoming the persistent myths that have taken root in the public psyche. Many parents still believe that vaccines cause autism, and celebrities like Jenny McCarthy and Jim Carey are giving public voice to their beliefs (1). As a result, public discourse on the subject of childhood vaccination has been largely misinformed, under-informed, and biased. Today, one in ten American parents refuse one or more vaccines for their children, and this is partially attributable to the anti-vaccine movement (1). Some American public schools have vaccination rates that are dangerously low and outbreaks of vaccine-preventable infectious diseases such as measles, whooping cough (pertussis), and mumps will continue if more parents decide not to vaccinate their children.

Vaccine opponents tend to believe that the risks of vaccination outweigh the risks of the diseases they protect against. This is largely due to the fact that vaccines have nearly eradicated most childhood communicable diseases in the United States, and thus the devastation of having a child die from an infectious disease has faded from the public psyche: “Public health specialists suggest that the resistance to vaccines is a consequence of the success of vaccinations. People, they say, no longer fear diseases they have never seen” (7). According to Robert Chen, who served as the head of immunization safety at the CDC, this is only natural. He graphed what happens when large-scale immunization programs are used for a long time, plotting public perception (See Figure 1 on page 69, from Chen and Orenstein, (8). In the pre-vaccine era, people are afraid of infectious diseases. Then, as vaccines are used and infection rates fall, people lose confidence in
vaccines and begin to fear the risks of vaccination more than the risks of infectious disease (8). Coverage rates subsequently fall, opening the door for outbreaks to occur (8). This is the phase that the United States is currently in. The past five years have witnessed outbreaks of measles, pertussis, and Hib across the country that have spread unchecked among children whose parents refused the standard childhood vaccines. Some children have died from vaccine-preventable diseases, yet the anti-vaccine movement continues to gain steam.

![Graph showing the evolution of immunization programs.](image)

**FIGURE 1.** Evolution of immunization programs.

Others in public health have echoed Chen’s theory of the natural history of an immunization program. Omer et al stated, “a reduction in the incidence of a vaccine-preventable disease often leads to the public perception that the severity of the disease and susceptibility to it have decreased. At the same time, public concern about real or perceived adverse events associated with vaccines has increased” (9). Omer et al’s statement is beautifully illustrated by Chen’s graph, and explains much of the current resistance to vaccines in the United States. Parents are making risk/benefit calculations.
based on a skewed perception of the risks of infectious disease, the risks of vaccination, and the benefits of protection from infectious disease. The role of the pediatrician in correcting this skewed view will now be addressed.

The Role of Pediatricians and Parents

Pediatricians are poised to do the most to change public perception of childhood vaccines. Data demonstrate that most parents seek out their child’s pediatrician as a primary source of knowledge about vaccines (10). As physicians with a fiduciary duty to their patients, pediatricians have a moral duty to educate hesitant parents and attempt to persuade them to vaccinate their child according to the medically recommended schedule. Some pediatricians have discharged from their care patients whose parents or guardians refuse to vaccinate their child. While discharging a patient who refuses to vaccinate may seem like an attractive option for various reasons, it is not the morally preferable course of action. There are alternative options that create an impetus for vaccination without discharge.

When children are placed at significant risk of disease by their parents, the right of a parent to make decisions for their child must be questioned: “Minors have a right to be protected against vaccine-preventable illnesses, and society has an interest in safeguarding the welfare of children who may be harmed by the choices of their parents or guardians” (11). Children are a vulnerable population: their parents serve as their surrogate decision makers and with that privilege comes the responsibility of making choices that are in the best interest of the child insofar as the parent is capable. Pediatricians should educate reluctant parents on the risks of vaccine refusal and to
attempt to persuade parents to vaccinate their child. Education on the risks of vaccine refusal will make the parent more capable of making the decision that is best for their child. A conversation with a pediatrician can do much to change a parent’s mind: Ball et al found that “provider behavior may be the most important determinant of immunization rates. The majority of parents follow their pediatrician’s recommendation regarding immunizations” (10). If a parent is persuaded to vaccinate his or her child, the child is protected from the harms of childhood communicable diseases and harms to vulnerable populations of children that may get a disease from an unvaccinated child are also prevented.

The American Academy of Pediatrics (AAP) recognizes the frequency with which pediatricians encounter parental refusal of vaccines, citing “85% of pediatricians report encountering a parent who refused or delayed one or more vaccines and 54% report encountering a parent who refused all vaccines” within one year in clinical practice (12). The AAP recommends that pediatricians discuss vaccine refusal risks in a non-condescending manner, allowing parents to voice their concerns (12). Diekema et al have suggested a way to effectively communicate with parents opposed to vaccination: “share honestly what is and is not known about the risks and benefits of the vaccine in question, attempt to understand the parent’s concerns about immunization, and attempt to correct any misperceptions and misinformation” (13). Better communication with parents will allow pediatricians to respect the autonomy of parents, to honor their fiduciary relationship with their patient, and to prevent harm to the best of their ability.

The AAP has released statements strongly against discharging patients on the grounds of vaccine refusal (12). To discharge a patient based on the preferences of his
or her parent(s) would violate the fiduciary duty that a pediatrician has toward his or her patient and is therefore not a morally preferable course of action. Every effort should be made on the part of a physician to preserve the fiduciary relationship they have with their patients. Patients will not benefit and may be harmed by losing their pediatrician, whereas patients will certainly benefit from a maintained relationship with their pediatrician, even if they lack immunity against infectious diseases. Additionally, a parent opposed to vaccination is not likely to be persuaded by a dismissive physician.

Both parents and pediatricians play seminal roles in the decision to vaccinate a child. Parents have a duty to educate themselves on the risks and benefits of vaccination and to make the best decision for their child as any surrogate health care decision maker should. Pediatricians have a duty to effectively communicate the risk/benefit balance of vaccination and strongly encourage parents to get their children vaccinated according to the recommended schedule.

**The Anti-Vaccine Movement and HPV Vaccine**

Anti vaccine activists have claimed that the HPV vaccine causes “strokes, blood clots, heart attacks, paralysis, seizures, chronic fatigue syndrome” and death (1). Some activists have gone on television programs with millions of viewers claiming, “this is an intervention that carries the risk of injury or death” (1). Of course, there are risks to every vaccine, but as was demonstrated in chapter 2, this is a gross exaggeration of the risks associated with the HPV vaccine, especially since the human papilloma virus doesn’t cause any of those symptoms: “the notion that a single viral protein could do all this - when the whole natural replicating virus can’t do any of it- is illogical” (1). Some
have even suggested that the vaccine can cause cancer, though as has already been discussed, this vaccine is safe because it doesn’t contain the viral genome that has to integrate into the genome of the cells lining the cervix in order to cause cancer (1). That the HPV vaccine would cause cervical cancer is a biological impossibility. As discussed in chapter 3, some parents and conservative groups are worried that the HPV vaccine will encourage promiscuity among young girls; one prominent anti-vaccine activist called the HPV vaccine the “slut shot” and “the cheaters’ vaccine” (1). However, since 70% of women are infected with HPV within five years of their first sexual encounter, and since studies have shown that fear of STIs does not play a significant role in timing of sexual debut, HPV and the associated risk of cervical cancer are certainly not limited to sluts and cheaters.

The anti-vaccine movement in America provides insight into this discussion of the HPV vaccine for several reasons. Perhaps the most important point to be gained from an understanding of the anti-vaccine movement is the need for more effective communication between the scientific community and the public on a macro level and between pediatricians and parents on a micro level. Communication of this sort is a part of public moral discourse, the means by which a society makes moral decisions. When public moral discourse is centered on rhetoric that is intended to misinform and sensationalize, as has been the case in the anti-vaccine movement, people tend to become polarized rather than reach compromise or understanding. Misinforming and sensationalizing rhetoric constitutes an unethical abuse of the power of language because it prevents people from bettering themselves and their society and it creates chaos in the place of compromise. This is problematic because in a democracy, an educated and
competent public is necessary for a government that truly functions ‘for the people and by the people.’ The power of unethical rhetoric to create chaos and damage society is perhaps nowhere better illuminated than in the anti-vaccine movement.

The brief summary of the anti-vaccine movement offered in this chapter demonstrates how sensationalized language and the unethical use of rhetoric to misinform can do irreparable damage to society. Even well meaning contributors to the public discourse do more damage than good when they use the power of language to disclose, not the truth, but a distortion, exaggeration, or even contradiction of the truth, despite the absence of evidence to support their claims. If a goal of our society is to establish a civil environment in which the best interests of all people are safeguarded, then people must have access to accurate information; access that parallels their access to misinformation, so that they can rationally sort through the melee themselves. Misinformation breeds fear, distrust, and chaos, and hinders shared understanding and compromise. If we are to protect the public health and prevent deadly infectious diseases from making a comeback in this country, then we must establish a language that accurately defines the risks and benefits of childhood vaccination and abandon misinformation altogether. Misinformation about the HPV vaccine has not been in short supply. From the way the vaccine was marketed to the way parents interpret the need for their daughter to be vaccinated, misinformation has been exchanged on all sides. Parents may feel their daughter doesn’t need the vaccine despite the data on the prevalence of HPV among adolescents with only one or two sexual partners, demonstrating the persistence of avidly held beliefs in the face of scientific evidence. One must understand the anti-vaccine movement to understand some of the opposition to mandating the HPV
vaccine, but there are certainly many who are not anti-vaccine yet are opposed to a mandate for the HPV vaccine; their arguments will be analyzed in chapter 5.
### TABLE 2: VACCINE COVERAGE IN THE UNITED STATES, 1999 AND 2009

<table>
<thead>
<tr>
<th>Vaccine (Disease)</th>
<th>Coverage by 24 months of age in US, 1999</th>
<th>Coverage by 24 months of age in US, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 or more doses of DTP or DTaP or DT (diphtheria, tetanus, pertussis)</td>
<td>95.7 +/- 0.5</td>
<td>94.6 +/- 0.7*</td>
</tr>
<tr>
<td>4 or more doses of DTP or DTaP or DT</td>
<td>81.5 +/- 1.0</td>
<td>79.8 +/- 1.1</td>
</tr>
<tr>
<td>3 or more doses of Polio (polio)</td>
<td>89.3 +/- 0.8*</td>
<td>91.3 +/- 0.8*</td>
</tr>
<tr>
<td>1 or more doses of MMR (measles, mumps, rubella)</td>
<td>90.5 +/- 0.8*</td>
<td>88.5 +/- 0.9*</td>
</tr>
<tr>
<td>3 or more doses of Hib (bacterial meningitis)</td>
<td>93.2 +/- 0.7</td>
<td>81.5 +/- 1.0</td>
</tr>
<tr>
<td>4 or more doses of Hib</td>
<td>76.3 +/- 1.1</td>
<td>50.9 +/- 1.4</td>
</tr>
<tr>
<td>3 or more doses of HepB (hepatitis B)</td>
<td>87.6 +/- 0.8</td>
<td>91.6 +/- 0.8</td>
</tr>
<tr>
<td>1 or more doses of Var (varicella virus- chicken pox)</td>
<td>54.6 +/- 1.2</td>
<td>88.9 +/- 0.8</td>
</tr>
</tbody>
</table>

**Combinations of Vaccines**

<table>
<thead>
<tr>
<th></th>
<th>Coverage by 24 months of age in US, 1999</th>
<th>Coverage by 24 months of age in US, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 DTP and 3 Polio and 1 MCV (MCV= measles containing vaccine)</td>
<td>77.9 +/- 1.0</td>
<td>76.8 +/- 1.2</td>
</tr>
<tr>
<td>4 DTP and 3 Polio and 1 MCV and 3 Hib</td>
<td>76.5 +/- 1.1</td>
<td>74.9 +/- 1.2</td>
</tr>
<tr>
<td>4 DTP and 3 Polio and 1 MCV and 3 Hib and 3 HepB</td>
<td>71.3 +/- 1.1</td>
<td>73.1 +/- 1.2</td>
</tr>
</tbody>
</table>

*The world health organization has estimated that 85% vaccine coverage is required to establish herd immunity against diphtheria, 94% for measles, 86% for mumps, 94% for pertussis, 93% for polio, and 87% for rubella. 1999 vaccine coverage rates were insufficient to establish herd immunity for measles and polio. 2009 vaccine coverage rates were insufficient to establish herd immunity for pertussis, measles, and polio.
<table>
<thead>
<tr>
<th>State</th>
<th>Outbreaks in the last 5 years</th>
<th>State</th>
<th>Outbreaks in the last 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>No</td>
<td>Montana</td>
<td>No</td>
</tr>
<tr>
<td>Alaska</td>
<td>No</td>
<td>Nebraska</td>
<td>No</td>
</tr>
<tr>
<td>Arizona</td>
<td>Yes- Pertussis, Measles</td>
<td>Nevada</td>
<td>No</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Yes- Measles</td>
<td>New Hampshire</td>
<td>No</td>
</tr>
<tr>
<td>California</td>
<td>Yes- Pertussis, Measles</td>
<td>New Jersey</td>
<td>Yes- Mumps</td>
</tr>
<tr>
<td>Colorado</td>
<td>No</td>
<td>New Mexico</td>
<td>Yes- Measles</td>
</tr>
<tr>
<td>Connecticut</td>
<td>No</td>
<td>New York</td>
<td>Yes- Mumps, Hib, Measles</td>
</tr>
<tr>
<td>Delaware</td>
<td>Yes- Pertussis</td>
<td>North Carolina</td>
<td>No</td>
</tr>
<tr>
<td>Washington, DC</td>
<td>Yes- Measles</td>
<td>North Dakota</td>
<td>No</td>
</tr>
<tr>
<td>Florida</td>
<td>No</td>
<td>Ohio</td>
<td>No</td>
</tr>
<tr>
<td>Georgia</td>
<td>Yes- Measles</td>
<td>Oklahoma</td>
<td>Yes- Hib</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Yes- Measles</td>
<td>Oregon</td>
<td>Yes- Pertussis</td>
</tr>
<tr>
<td>Idaho</td>
<td>No</td>
<td>Pennsylvania</td>
<td>Yes- Measles, Hib</td>
</tr>
<tr>
<td>Illinois</td>
<td>Yes- Pertussis, Measles</td>
<td>Rhode Island</td>
<td>No</td>
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<tr>
<td>Indiana</td>
<td>Yes- Measles</td>
<td>South Carolina</td>
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<tr>
<td>Iowa</td>
<td>No</td>
<td>South Dakota</td>
<td>No</td>
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<tr>
<td>Kansas</td>
<td>No</td>
<td>Tennessee</td>
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</tr>
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<td>Kentucky</td>
<td>No</td>
<td>Texas</td>
<td>No</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Yes- Measles</td>
<td>Utah</td>
<td>No</td>
</tr>
<tr>
<td>Maine</td>
<td>Yes- Hib</td>
<td>Vermont</td>
<td>Yes- Pertussis</td>
</tr>
<tr>
<td>Maryland</td>
<td>No</td>
<td>Virginia</td>
<td>Yes- Measles</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>No</td>
<td>Washington</td>
<td>Yes- Pertussis, Measles</td>
</tr>
<tr>
<td>Michigan</td>
<td>Yes- Measles</td>
<td>West Virginia</td>
<td>No</td>
</tr>
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<td>Minnesota</td>
<td>No</td>
<td>Wisconsin</td>
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</tr>
<tr>
<td>Mississippi</td>
<td>Yes- Pertussis</td>
<td>Wyoming</td>
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</tr>
<tr>
<td>Missouri</td>
<td>Yes- Measles</td>
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</tbody>
</table>
References, Chapter 4


A PRINCIPLE BASED ANALYSIS OF WHY HPV VACCINE MANDATES ARE NOT THE IDEAL LEGISLATIVE SOLUTION

The goal of public health policy is to improve the nation’s health for the betterment of society. When considering mandatory public health interventions, legislators should allow bioethics to guide their decisions about the morality of proposed programs. Nancy Kass has suggested an ethics framework to guide public health policy decisions (1). Kass suggests that lawmakers follow a six step framework in which they discern, first, the goals of the proposed public health intervention, which ought to include the reduction of morbidity/mortality of disease; second, the effectiveness of the proposed public health program at achieving its goals; third, the potential burdens of the proposed public health program; fourth, the possible means of minimizing the potential burdens and whether or not there are any alternative programs that might accomplish the same goal but with lesser burdens; fifth, whether or not it’s possible to implement the program fairly; and finally, how the benefits and burdens of the program can be fairly balanced (1).

This chapter seeks to analyze a proposed HPV vaccine mandate for girls entering sixth grade that includes a broad parental opt-out provision (similar to the mandates implemented in VA and DC) using an approach that takes into account all of Kass’ suggestions. I propose that the goals of a proposed public health program as well as the effectiveness of the proposed program (Kass’ first two steps) may be evaluated using the concept of a public health necessity. The concept of a public health necessity was first
cited in *Jacobson v. Massachusetts* (1905) and, loosely defined, indicates the presence of a significant threat to the public’s health. Legislators should identify a public health necessity for HPV vaccine mandates before implementing them. I will establish that HPV does not constitute a public health necessity in the United States and that although HPV vaccine mandates meet Kass’ first criterion since the ultimate goal is reduction in the morbidity and mortality of cervical cancer, her second criterion is not met since we have insufficient data to know for sure how long the vaccine confers immunity and therefore we don’t know how effective vaccine mandates will be at lowering cervical cancer morbidity and mortality.

In addition to an evaluation of the presence of a public health necessity, legislators should balance prominent bioethics principles in making decisions about what public health interventions are appropriate. Therefore, a principle-based moral theory of bioethics will guide this discussion. The seminal principle-based moral theory of bioethics was put forward by Beauchamp and Childress in *Principles of Biomedical Ethics*, of which there are several editions (2). HPV vaccine mandates will be analyzed in the context of the established bioethical principles of beneficence, respect for autonomy, and justice. Using the principles of beneficence and respect for autonomy, I will address Kass’ admonition to analyze the potential burdens of a proposed public health program as well as any possible means of minimizing those burdens (her second and third steps). I will address considerations of social and distributive justice using the principle of justice (Kass’ fifth step) and finally I will attempt to fairly balance all of these considerations, as Kass does in her sixth step in the framework. I will conclude that none of Kass’ criteria numbered 3 through 6 are met because mandates do not provide
sufficient public health benefit to justify their financial and moral costs, because the potential burdens of an HPV vaccine mandate can be minimized through alternative, voluntary vaccination programs that confer similar public health benefits as mandates without coercion, and because in the absence of a public health necessity, it is unfair and unjust to impose the burdens of a vaccine mandate on the public. Therefore, the principles of beneficence, respect for autonomy, and justice are not satisfied by a state-mandated HPV vaccination program and thus school-based HPV vaccine mandates are not the optimal legislative solution.

Public health officials have a moral duty to act beneficently toward the populations they serve. Kass attests to this, stating “public health has an affirmative obligation to improve the public’s health and, arguably, to reduce certain inequities” (1, emphasis original). However, this does not mean that public health officials have a moral obligation to implement every single plausible public health program since part of acting beneficently toward the public is weighing options and implementing those programs that will most benefit the public. In other words, a failure by lawmakers to implement legislation with the goal of increasing HPV vaccine availability and uptake as a means to reducing the morbidity and mortality of cervical cancer is not a failure to act beneficently towards civilians or a failure to maximize distributive justice to the greatest extent possible, as long as lawmakers implement other public health programs that will benefit civilians more and maximize distributive justice to a greater extent than an HPV vaccination program would. Lawmakers have a moral obligation to act beneficently toward their constituents, which requires that they carefully consider proposed public health programs and implement only those that confer greater benefits than burdens on
the public. HPV vaccine mandates do not meet this standard, and therefore public health officials and legislators should pursue other, more beneficial and less coercive public health measures.

**Public Health Necessity: Goals and Effectiveness of HPV Vaccine Mandates**

Kass’ first two criteria for an ethics analysis of a proposed public health program are an analysis of, first, the goals of the proposed public health program and second, the effectiveness of the proposed program at achieving those goals. Kass argues that the primary goal of a proposed public health intervention ought to be the reduction of morbidity and/or mortality of disease. The ultimate goal of an HPV vaccine mandate is cancer prevention, an indisputable good, but there are differing opinions about how best to accomplish this goal and about whether or not the prevention of cervical cancer through vaccination is a significant enough good to justify overriding autonomy and spending public money on a mandate. Furthermore, it is not known for certain how effective HPV vaccine mandates will be at reducing the morbidity and mortality of cervical cancer since we lack longitudinal data including for how long the vaccine confers immunity and whether or not it will have a significant impact on cervical cancer in the United States, where the morbidity and mortality of cervical cancer are low. A significant question that Kass does not raise in her framework is whether or not the morbidity and mortality of the disease to be prevented is a significant enough burden on the population to justify a mandatory public health program. In order to address this question, the concept of a public health necessity will be used.
As previously stated, the concept of a public health necessity was first cited in *Jacobson v. Massachusetts* (1905) and, loosely defined, indicates the presence of a threat to the public’s health (3). The *Jacobson* court concluded that it was appropriate for the state to compel citizens to be vaccinated against smallpox against their will based on the existence of a public health necessity: “Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” (3). In essence, this ruling stated that citizens could be compelled to undergo vaccination if it protected the entire community against a health threat (3). Diseases that present a public health necessity are most commonly casually communicable (meaning the disease is passed through casual, everyday contact like breathing in the same vicinity as an infected person or shaking their hand), extremely contagious, and pose a high risk of imminent and substantial harm.

The burden of proof in demonstrating the presence of a public health necessity, which provides the justification for a mandatory public health program, lies with the government. Kass presents the reasons for this: “because many public health programs are imposed on people by governments and not sought out by citizens, the burden of proof lies with governments or public health practitioners to prove that the program will achieve its goals” (1). Citizens have a prima facie right to autonomy that should not be infringed upon without justification; prima facie rights should only be overridden under circumstances that present unjustifiable harm to others (2). Circumstances that present a risk of unjustifiable harm to others include exposure to people who have not been vaccinated against infectious diseases that constitute a public health necessity because they are casually communicable, highly infectious, and imminently dangerous. These
include measles, mumps, rubella, diphtheria, tetanus, pertussis, Hib, polio, and heptatis B. Failure to vaccinate a child with the MMR, DTaP, Hib, Polio, and HepB vaccines constitutes an unjustifiable risk of harm to the child and to all those in the child’s social circle, especially if that child lives in an area with a high non-medical vaccine exemption rate (4). For these vaccines, a public health necessity is present and it is therefore justifiable to override parental autonomy by mandating these vaccines in order to protect children and the public from serious infectious diseases. Because the threat of these diseases constitute public health necessities, broad opt-outs for these vaccines that would allow parents to refuse them for any reason would not be appropriate and revoking the social right of attending a public school in cases of non-compliance is appropriate.

HPV does not pose a public health threat that is as serious as measles and the other casually communicable diseases listed above. HPV poses a very small public health threat in the United States because despite the fact that infection rates are high and HPV is extremely contagious, HPV is neither casually communicable nor imminently dangerous and it does not pose a high risk of substantial harm. The risk of developing cervical cancer, a substantial harm, from HPV infection is quite low. For these reasons, HPV does not present a public health necessity and states should not mandate the HPV vaccine. Several characteristics of the HPV vaccine make it significantly different from the other vaccines that have been mandated for children entering school in this country. HPV does not pose an imminent risk of danger, it protects against cancer that may develop decades down the road, and it is sexually transmitted and should therefore not be passed from child to child in school. Additionally, the chances of developing cervical cancer if one contracts HPV are smaller than the chances of developing disease and
sequelae if one contracts other infectious diseases for which vaccine mandates are in place, such as measles or pertussis. Children should not be kept out of public school because of their HPV immunization status since being unvaccinated against HPV does not pose any risk of imminent danger to other students. The HPV vaccine does not present a risk of harm significant enough to justify overriding parental autonomy. HPV does not present a public health necessity because it is not casually communicable and it poses low risk of substantial harm decades down the road. This is not to say that HPV is not an important public health concern. Indeed, the morbidity of cervical cancer and cervical cancer precursors derived from HPV is quite high and we have screening programs and cancer treatment advances to thank for the reduced mortality of cervical cancer in the United States.

School-based mandates keep children out of public schools in cases of non-compliance. Recall from chapter three that the precedent for school-based vaccine mandates is rooted in Zucht v King. Prior to Zucht v King, the Jacobson court considered compulsory vaccination, which involves the forcible vaccination of people who refuse to comply, but the Zucht court considered mandatory vaccination, which involves denying social privileges, such as attending public school, to those people who refuse to comply (4). Mandatory vaccination has been upheld in US courts as a better use of state power than compulsory vaccination since mandatory vaccination gives the citizen a choice: get the vaccine, or lose a social privilege (4). However, when the social privilege lost is attendance at public school, the stakes are so high that one must consider whether a parent (especially a parent of limited means) actually has a practical choice in the matter. It is a testament to the importance of childhood vaccines in protecting the
public’s health that the US Supreme Court decided that it was constitutional to impose such a mandate. However, the HPV vaccine does not meet this same standard: HPV doesn’t present enough of a public health threat for states to revoke social rights or privileges if a parent chooses not to vaccinate their child. Children should not be kept out of public schools due to their HPV immunization status. While highly infectious diseases such as measles, pertussis, and Hib present a public health threat that justifies revoking the privilege of public school in cases of noncompliance, HPV does not since HPV infection does not pose a significant risk of imminent danger or harm to other students.

Although the established lack of a public health necessity in the case of HPV suggests that states should not mandate the HPV vaccine for girls in public schools, the mandates that have been passed in Virginia and DC are morally and ethically acceptable thanks to the presence of broad parental opt-outs in the mandates. These mandates prevent harm by vaccinating as many young girls as possible (maximizing distributive justice) while still attempting to respect parental autonomy. It is a very small violation of parental autonomy to ask a parent to say no to a vaccine for their child when they are given the chance to say no for any reason, are not required to provide reasons for their declining the vaccine, and are given the option to refuse it in a convenient and reasonable manner. The broad opt-out provisions that have been included in the DC and Virginia HPV mandates prevent children from being kept out of school due to their HPV vaccination status. However, significant concerns are that either the opt-outs could weaken over time, making the mandates implemented in VA and DC unacceptable, or that the opt-outs could seep into other vaccine mandate legislation, thereby endangering public health by weakening mandates that protect the public against casually
communicable, imminently dangerous infectious diseases. The presence of broad opt-outs in a mandate does not address all the mitigating factors that make the HPV vaccine so different from previously mandated vaccines, and therefore is not the optimal legislative solution. Furthermore, broad opt-outs will weaken the effectiveness of the vaccine at accomplishing the goal of cancer prevention if a significant number of parents opt-out of the vaccine.

The first two criteria Kass suggests that lawmakers considering a proposed public health program discern are, first, the goals of the proposed public health intervention, which ought to include the reduction of morbidity/mortality of disease and second, the effectiveness of the proposed public health program at achieving its goals. HPV vaccine mandates meet Kass’ first criterion because the ultimate goal of an HPV vaccine mandate is to reduce morbidity and mortality of disease, but the lack of a public health necessity precludes the need for a mandate in the first place. Legislators should identify a public health necessity before implementing mandatory public health programs and since HPV does not present a clear case of a public health necessity, legislators should seek alternative means of achieving the same benefits of reduction in the morbidity and mortality of cervical cancer through less coercive means. Since longitudinal data is still lacking, it is not known that mandates will be effective at achieving the goal of cancer prevention, and thus we have insufficient data to determine whether or not Kass’ second criterion is met.
Beneficence and Respect for Autonomy: Balancing Burdens and Benefits

Kass’ third and fourth steps call for the consideration of any potential burdens of a proposed public health program and any possible means of minimizing those burdens. The potential burdens of an HPV vaccine mandate may be discerned using the principles of beneficence and respect for autonomy. Beauchamp and Childress define beneficence as “contributing to the welfare of others,” differentiating between positive beneficence, which “requires agents to provide benefits to others” and utility, which “requires that agents balance benefits, risks, and costs to produce the best overall results” (2). The goal of public health is to pursue measures that will improve the health of a community, so from a public health perspective, utility is more important than positive beneficence because legislators should implement laws and programs that benefit the community as a whole. Beauchamp and Childress also claim that some acts of beneficence are obligatory, and they cite vaccine mandates among them: “Preventive medicine and public health interventions have long embraced concerted social actions of beneficence, such as vaccination programs... as obligatory, not merely optional” (2). The beneficent act of submitting one’s self to vaccination in order to protect the welfare of the community is more important than a person’s right to refuse treatment due to the fact that the magnitude of benefits and risks of vaccination to the community far outweigh the magnitude of the benefits and risks of vaccination to the individual. However, this only holds true for imminently dangerous infections like measles, Hib, pertussis, etc. HPV is not imminently dangerous to anyone who contracts it and unlike other infectious diseases, people have control over whether or not they engage in sexual behaviors that put them at risk for contracting HPV. For these reasons, HPV vaccination is not morally
obligatory for citizens, although vaccination against other infectious diseases is. An analysis of the benefits, risks, and costs of the vaccine to the individual as well as the benefits, risks, and costs of the vaccine to the public are analyzed below in the contexts of beneficence and respect for autonomy.

Evidence presented in chapter 2 demonstrates that the HPV vaccine provides effective and safe protection from infection with HPV strains 16 and 18, which are responsible for 70% of cervical cancers. Current knowledge of the HPV vaccine demonstrates that the vaccine provides high prospect of benefit for girls prior to exposure to HPV and a low risk of harm to individuals who are vaccinated. Additionally, the magnitude of the benefit, preventing cancer, is greater than the magnitude of the risk of harm, which includes mostly benign and short-lived side effects. The financial cost of the HPV vaccine for an individual varies, depending on what state they live in, whether or not the state has mandated the vaccine be covered by insurance, and what type of insurance they have. These costs range from free to the full cost of $360 (5). These are the benefits, risks, and costs of the HPV vaccine in individuals, but the benefits, risks, and costs of an HPV vaccine mandate to the public are quite different.

The primary benefit to the public of an HPV vaccine mandate would be widespread protection from the HPV strains included in the vaccine and the establishment of herd immunity against these viruses, which would result in lower rates of cervical cancer and other HPV-derived cancers in the population. The long-term goal of the HPV vaccine, that of cancer prevention, is an indisputable benefit to society (6). The increased availability and uptake of vaccine that occurs any time a vaccine is mandated and insurers are forced to cover the vaccine would aid in the establishment of
herd immunity. However, if the most persuasive argument in favor of a mandate is to increase access, then we must question the entire system of how vaccines are purchased and distributed in this country. In other words, while making the vaccine more available to the public than it otherwise would be is indeed a consequence of a vaccine mandate, the vaccine could potentially be made more available to the public through other means, such as New Hampshire’s state-funded HPV vaccine program, which provides the HPV vaccine to all girls between eleven and eighteen years of age completely free thanks to funding from a combination of federal and private sources. If alternative programs can accomplish the benefits of herd immunity and increased access for society without restricting parental autonomy, that would be morally preferable.

The primary risk to states associated with an HPV vaccine mandate is that of public backlash, as was demonstrated in Texas following the governor’s mandate. However, the jurisdictions that have successfully mandated the HPV vaccine, DC and VA, have done so without public backlash thanks to the broad opt-out provisions discussed in chapter 3. As discussed in chapter 2, the financial costs of an HPV vaccine mandate would be reasonable in the target population, eleven and twelve year old girls. The vaccine has been found cost effective in eleven and twelve year old girls at that rate of approximately $30,000 spent per QALY gained, which is low compared to other cancer prevention measures like screening programs, although the vaccine does not preclude the need for screening programs (7, 8, 9). Although a vaccine mandate would not save money by precluding the need for cervical cancer screening, it may save money by preventing the need for costly treatment of cervical cancer. A mandate may present states with other costs, including potential diversion of funds from other worthwhile
public health measures or legislative goals as well as the costs to school systems required for the logistical process of enforcing mandates and the costs of time and effort to parents who choose to opt-out of those mandates. Mandate opponents have pointed out that “adding HPV (to the list of state-mandated vaccines) could drive more states to abandon funding for other vaccinations and could divert funding from other important public health measures” (10). Notably, a mandate would not impose additional costs to state entitlement health insurance programs like Medicaid and Vaccines for Children, because these entitlement programs already cover the vaccine since they cover all ACIP recommended vaccines for children (11). The benefits, risks, and costs of an HPV vaccine mandate to the public are such that legislators could ethically mandate the HPV vaccine according to the principle of beneficence, but if the same benefits could be achieved at lower cost or lower risk through alternative programs, that would be morally preferable. Alternative programs, however, will all present unique benefits, risks, and costs to the public as well, and should by no means be thought of as a free and no-risk solution to the problems of vaccine mandates. Javitt et al favor alternative programs, pointing out that “mandates are not the only way to increase parental awareness or achieve insurance coverage” (10). To this end, as reviewed in chapter 3, many states have allocated state funding to educational programs to increase awareness of the HPV vaccine.

Thus, an analysis of the ethics of HPV vaccine mandates using the principle of beneficence provides an endorsement of an HPV vaccine mandate since a vaccine mandate is one means of pursuing the beneficent goal of cancer prevention. If each citizen beneficently submits to vaccine mandates, the community will greatly benefit
from the establishment of herd immunity, which will be made possible partly through the increased access to the vaccine and increased uptake of the vaccine that would result from a mandate. However, this is a weak endorsement of vaccine mandates since there are less coercive means of providing the same benefits to the public that a mandate would provide, but with different costs and potentially lower risks. The state has a valid interest in preserving and protecting the health of its children, but implementing an HPV vaccine mandate is not in the best interest of citizens.

Considerations of respect for autonomy are particularly complicated when considering an HPV vaccine mandate because there is a vulnerable population involved, specifically children whose parents are their surrogate decision-makers. Parents have a special obligation to act beneficently toward their children (2). As surrogates, parents should employ the best interests standard of decision-making since children have not yet developed their own mature set of values and goals and therefore the child’s relevant preferences are not known and substituted judgment is not feasible (2). Parental decision making in the clinical context employs the best interests standard of surrogate decision making in order to weigh the risks and benefits of the treatment suggested, in this case vaccination against HPV. Since an HPV vaccine mandate assumes that what is best for girls is immunity from HPV, mandates unavoidably impose a belief system on parents who may or may not hold the view that getting vaccinated is what is best for their daughter. On the other hand, allowing their child to get vaccinated will not impede parents from teaching social and moral values to their children and it is not likely that girls who receive the vaccine will engage in sexual activity that they wouldn’t have otherwise engaged in. Furthermore, although children lack true autonomy and the ability
to provide informed consent, the assent of a child should be sought in appropriate circumstances, although the assent of a child is not necessary for vaccination. It is important to note that parental autonomy as surrogate decision-makers for their children is limited in ways that personal autonomy is not: the scope of what parents can refuse for their children is smaller than what persons can refuse for themselves. While parental autonomy is important, the burdens and benefits of both infectious disease and vaccination are carried primarily by the child: “Minors have a right to be protected against vaccine-preventable illnesses, and society has an interest in safeguarding the welfare of children who may be harmed by the choices of their parents and guardians” (12). The state has an interest in preserving the lives of its children with prophylactic health interventions. However, parental autonomy should only be overridden if a failure to vaccinate their child would carry the risk of unjustifiable harm to others. Since an adolescent being unvaccinated against HPV does not pose a health threat to other adolescents unless they choose to engage in sexual contact with them, it is an unjustified breach of parental autonomy to require parents to get their daughters vaccinated. As previously discussed, the broad opt-outs included in the VA and DC mandates attempt to address this problem by allowing parents to opt out of the vaccine for their daughter, but this is not the optimal legislative solution since the opt-out may weaken over time, seep into other vaccine mandates, or simply be poorly advertised and therefore practically nonexistent for less savvy parents. As established earlier, no public health necessity exists in the case of HPV and a failure to vaccinate a child against HPV does not constitute an unjustifiable risk of harm to others.
One reason parents have authority over their children is rooted in beneficence (2). Beauchamp and Childress frame the role of beneficence in parental authority nicely: “We do not control children because we believe that they will subsequently consent to or would rationally approve our interventions. We control them because we believe they will have better, or at least less dangerous, lives” as a result of our interventions (2). The greatest stake-holder in the decision of whether or not to vaccinate a child against HPV is the child, who will bear the risks of vaccination and later in life may reap the benefits of vaccination (3). However, since children lack autonomy and since the parent is the recognized surrogate decision-maker for the child, respecting parental autonomy is morally desirable. HPV vaccine mandates, even those that include broad opt-out provisions, limit parental autonomy by requiring parents to have their children vaccinated or take some action demonstrating that they choose to opt-out of the mandate.

Some parents have opposed HPV vaccine mandates on the premise that they constitute a violation of privacy. This has legislative roots: the first case to “construe the right to privacy not only as shielding information from others, but as protecting an area of individual and familial freedom from governmental interference” was Griswold v. Connecticut (1965), a contraception case (2). Privacy is closely linked with autonomy because one way we conceptualize our right to privacy is as a right to self-governance and freedom from outside control, which is largely how autonomy is defined. Many parents view adolescent sexuality as an area of familial privacy, but the state has a valid interest in educating and protecting adolescents who engage in sex. HPV vaccine mandates do not lack justification because they violate privacy, they lack justification because there is not a public health necessity for them and therefore imposing the risks,
burdens, and costs of a mandatory vaccination program on the public will not benefit the public enough to justify a mandate.

One opponent of HPV vaccine mandates claims that they disrespect autonomy by attempting to regulate behavior. Heather Harrell argues in the Journal of Law, Medicine, and Ethics that HPV vaccine mandates are immoral on the grounds that they constitute behavior regulation in the name of public health. Harrell claims that “HPV vaccine mandates are behavior regulation in the sense that the mandates affect how individuals engage in sexual activity and equate to government requiring one behavioral choice over others that may be equally efficacious” (13). Just because the HPV vaccine protects against an STI doesn’t mean that mandating the vaccine constitutes regulation of sexual behavior. Harrell provides no evidence that girls who have received the HPV vaccine make sexual behavior choices any differently than girls who have not received the HPV vaccine, and in fact, data on other STI prevention measures indicate that education tends to delay age at sexual debut and produce safer sex practices (14). Requiring girls to be vaccinated against an STI that can cause cancer is not the same as the government advocating promiscuity or denouncing sexual abstinence. HPV vaccine mandates are primarily an issue of public health, while the issues of privacy rights raised by HPV vaccine mandates are secondary. Once again, HPV vaccine mandates are not immoral because they constitute behavioral regulation or invasion of privacy, but because there is not a public health necessity for protection from HPV.

Kass admonishes legislators considering proposed public health measures to consider third, the potential burdens of the proposed public health program and fourth, the possible means of minimizing the potential burdens and whether or not there are any
alternative programs that might accomplish the same goal but with lesser burdens. An analysis of HPV vaccine mandates using the principles of beneficence and respect for autonomy has demonstrated that the potential burdens of an HPV vaccine mandate can be minimized through alternative, voluntary vaccination programs that confer similar benefits as mandates. Therefore, legislators should not implement HPV vaccine mandates.

**Justice**

The fifth consideration Kass suggests is a determination of whether or not it’s possible to implement the proposed public health program fairly. An egalitarian understanding of the principle of justice will guide this discussion. Beauchamp and Childress define justice using a concept of social distributive justice, which “refers broadly to the distribution of all rights and responsibilities in society, including civil and political rights” (2). In a health care context, distributive justice refers to the “fair, equitable, and appropriate” distribution of health care resources as “determined by justified norms that structure the terms of social cooperation” (2). Based on this definition, which is an egalitarian definition of justice, are HPV vaccine mandates just? That is, are they an ethically appropriate and morally desirable course of action for states?

Before determining whether or not an HPV vaccine mandate is just, we must ask whether or not it is unjust. Actively withholding HPV vaccine from a population would be unjust because it would deprive people of making the autonomous choice to receive an intervention that may offer them benefit. However, a failure to implement a mandate or
alternative program is not the same as actively withholding the vaccine. Individuals may feel that a mandate is unjust, but that has more to do with violations of respect for their autonomy than justice since concepts of justice address the benefits and burdens of a mandate to populations, while autonomy addresses the benefits and burdens of a mandate to individuals.

An analysis of the principle of justice from an egalitarian view leads to the conclusion that HPV vaccine mandates will increase vaccine uptake and access, thereby encouraging the fair, equitable, and appropriate distribution of health care resources. It has been noted by many that “mandates are the most effective way of ensuring accessibility for young people and achieving widespread protection against disease” (3). Importantly, mandates are the best means of ensuring vaccine uptake and access among those populations that can most benefit from the vaccine because they disproportionately bear the burden of cervical cancer due to lower access to screening (3). Of course, these populations are also the least likely to be able to exercise their right to opt-out of a vaccine mandate, but that is a lesser concern than the fact that without mandates, they likely won’t be able to choose to get vaccinated, either. Social justice is best served when programs that are realistic to implement are favored by legislators since realistic programs are most likely to successfully encourage the equitable distribution of the program’s benefits as well as the rights and responsibilities that the program entails. Implementing school mandates for the HPV vaccine is much more realistic than completely revamping the way vaccines are manufactured, licensed, insured, and provided in the United States. Indeed, the costs to the public of revamping these systems would most likely outweigh the costs of mandating the HPV vaccine. A revamping of
vaccine policies may be necessary in the future, however, as more prophylactic cancer vaccines that do not protect against imminently harmful infections become available. Despite the fact that school mandates are one way to maximize social justice in the dissemination of vaccines, alternatives exist that are morally preferable since they would increase access and uptake of the HPV vaccine, thereby conferring all the benefits of the vaccine on the public without the financial and moral costs of a mandate. Although mandates encourage distributive justice, it is not just to impose mandates on the entire population, thereby restricting the autonomy of a large number of people, in order to ensure the protection of the most vulnerable segments of the population. Alternatives like educational programs and the Vaccines for Children program exist that are intended to increase vaccine access and uptake among the most vulnerable populations. These alternative means of reaching the most vulnerable populations are entirely voluntary and a more appropriate way for public health officials to address HPV and cervical cancer in the United States.

A gender-based mandate is just in the case of the HPV vaccine. Considerations of justice inherently include considerations of balancing costs since it would be immoral to place the burden of unjustified costs, be they financial or otherwise, on society. Although the HPV vaccine is effective at protecting against HPV in boys and should be available to boys on a voluntary basis, a mandate that required boys to get the vaccine would place an undue burden of cost on society since the vaccine has been found to not be cost effective in boys (9). Additionally, the risks of going unvaccinated outweigh the risks of vaccination for any individual girl who as a woman will face the risk of cervical cancer, but the risks of vaccination may outweigh the risks of foregoing vaccination for any
individual boy or man, since HPV-derived cancers in men are extraordinarily rare (9).

Boys could, of course, be required to get the vaccine in order to prevent them from acting as viral vectors, spreading HPV among women, but it is more cost effective and more morally appropriate to vaccinate women since women stand to gain the most benefit from vaccination and therefore should bear the risks associated with vaccination. Some mandate opponents have concerns that a gender specific mandate may violate constitutional principles of equality since females, but not males, would be gaining the protection of the state. This seems to violate the equal protection clause of the 14th amendment of the U.S. Constitution, which prohibits states from denying any citizen the equal protection of the laws (15). Pizzitola evaluated the validity of a potential equal protection claim and found that such a claim would not be viable in the case of the HPV vaccine being mandated for girls and not boys (15). This is because states must establish that there is “exceedingly persuasive justification” for the unequal protection of the law (15). Young girls, but not young boys, will later in their lives be at risk of developing cervical cancer if they contract HPV (15). Additionally, the risks of males developing HPV-derived cancers of the anogenital region are substantially lower than females’ risk of developing HPV-derived cervical cancer. Finally, the HPV vaccine has been found to be cost effective only when administered to adolescent girls prior to their sexual debut. These three facts build an exceedingly persuasive justification for the unequal impact of the law in this case, and therefore states have a legitimate reason for implementing a gender-specific mandate of the HPV vaccine. Therefore, it is unlikely that a gender-based HPV vaccine mandate would be found unconstitutional (15).
Although there is a legitimate and persuasive reason to mandate the HPV vaccine for only one gender, the greatest justification for a mandate using the principle of justice is that a mandate is the most effective tool available for promoting social justice in access to the HPV vaccine. This is an insufficient justification since alternative means of increasing access that are less coercive exist and since HPV does not constitute a public health necessity. Kass’ fifth criterion, that legislators determine whether or not the proposed public health program can be implemented fairly, is not met. In all of public health, burdens are imposed on the collective community as a whole in order to protect a few individuals, but this is justifiable because there is no way vulnerable persons may protect themselves from epidemics of casually communicable diseases and therefore an unjust endangerment of public health is present and a public health necessity exists. In the absence of a public health necessity, it is unfair and unjust to impose the burdens of a vaccine mandate on the public. Maximizing public access to a vaccine that is already readily available is not a sufficient justification to implement a mandate in the absence of a public health necessity.

**Conclusions and Recommendations**

Public health is about trade-offs. We do not have unlimited resources for implementing every potential program that may benefit the public’s health. Applying Kass’ ethics framework for analyzing potential public health programs is a good way to ensure that implemented programs are worthwhile and morally acceptable. HPV vaccine mandates do not meet several of Kass’ six criteria. Kass’ first criterion is met because the ultimate goal of an HPV vaccine mandate is to reduce morbidity and mortality of disease,
but the lack of a public health necessity precludes the need for a mandate in the first place. We have insufficient data to determine whether or not Kass’ second criterion is met since longitudinal data is still lacking and it is not yet known that mandates will be effective at achieving the goal of cancer prevention. HPV vaccine mandates do not satisfy Kass’ third and fourth criteria because the potential burdens of an HPV vaccine mandate can be minimized through alternative, voluntary vaccination programs that confer similar public health benefits as mandates without coercion. HPV vaccine mandates also fail to meet Kass’ fifth criterion, that the proposed public health program can be implemented fairly. In the absence of a public health necessity, it is unfair and unjust to impose the burdens of a vaccine mandate on the public. Finally, Kass calls on legislators to fairly balance the benefits and burdens of the proposed public health program. This can’t be done with an HPV vaccine mandate, since it would be unfair to impose the burdens of a vaccine mandate on the public in the absence of a public health necessity, especially when less coercive, voluntary alternatives exist that will achieve similar public health protection through less coercive means.

The HPV vaccine is unique: it is the first vaccine created with the primary goal of cancer prevention through conferring immunity to a virus, it is the first vaccine that protects against an STI that does not pose the threat of imminent danger as Hepatitis B does, and it is the first vaccine to be mandated for school children that isn’t transmissible in a school setting. The unique case of the HPV vaccine has sparked a national debate. The most constructive way to debate mandating the HPV vaccine is to focus on re-evaluating the proper role of vaccine mandates in schools and public health more broadly. The debate has been affected by the fact that a personal behavior choice to remain
abstinent from sex can protect a person from exposure to HPV. In an article exploring the modern day ramifications of *Jacobson v Massachusetts* (1905), James Colgrove noted the recent rise in public awareness of the impact of behavioral health on the community: “As personal behavior became a more prominent explanation for patterns of morbidity and mortality during the last decades of the 20th century, the tension between the individual and the collective well-being was recast. The threat to the community became the feckless behavior of individuals whose ‘lifestyle choices’ cost society money in health care and lost productivity” (4). Colgrove explores issues such as motorcyclists refusing to wear helmets, drivers refusing to wear seat belts, and smokers smoking in public places to demonstrate the dichotomy between the perception of the individual that the government is being paternalistic by coercing them to change their behavior and the perception of the courts and the public that the individual’s reckless actions are imposing costs on the community in a multitude of ways (4). A similar phenomenon can be seen with the HPV vaccine: some individual parents feel that the government is unduly intruding into their private family lives by mandating vaccination against HPV, while other citizens feel that if we can prevent or reduce the personal and community costs of cervical cancer and other HPV-related diseases, then we should. As more and more diseases like obesity, diabetes, hypertension, and certain cancers are found to be related to behavioral choices, our society must confront the conflict between individual and community interest. Recall from chapter 1, John Stuart Mill’s social contract theory: “society should permit individuals to develop according to their own convictions, as long as they do not interfere with a like expression of freedom by others or unjustifiably harm others” (2). According to this argument, citizens of a just society may make autonomous
decisions about their own lives insofar as they do so without causing unjustifiable harm to others or interfering with other citizens’ freedom to similarly live autonomously (2). Is a decision to have sex that subsequently results in HPV infection and later development of cervical cancer an unjustifiable harm to society? Is a decision to overeat and remain sedentary that subsequently results in obesity and diabetes an unjustifiable harm to society? Does the magnitude of the harm change when thousands of people make these choices and society supports them? These are questions that public health will have to face in coming years, and the ethical concepts that have guided this analysis of mandating the HPV vaccine will be useful in those policy discussions.

Another issue associated with the HPV vaccine that has been widely debated is its non-transmissibility in a school setting. Public schools were historically chosen to be the enforcement mechanism for vaccine mandates not because students transmit infections to one another at school, but because it was the most effective way to reach the majority of the population (5). History aside, it is legitimate to question whether or not public schools are an appropriate enforcement mechanism for public health measures; should vaccines have to protect against diseases children get at school to be implemented in a school setting? School vaccine mandates undoubtedly have been effective at reducing the prevalence of infectious diseases, but it is unknown how much of this is attributable to the large population reached through public schools or if it is attributable to preventing children from spreading infections at school. The success of school-based vaccine mandates is likely a consequence of both.

HPV vaccine is the first vaccine designed primarily to protect against cancer, but hopefully more will become available in coming years. If school mandates are not
appropriate for the HPV vaccine and other potential cancer vaccines, then we will need another means of increasing public access to these potentially life-saving vaccines. This is a daunting task since vaccine mandates have not been enforced through means other than school systems since smallpox was a public health threat and health officials literally went door-to-door with the vaccine (5). Since the public school system is already established nationwide and has been proven effective at implementing public health initiatives in the past, it is tempting to take advantage of the infrastructure we already have to make vaccine uptake near universal, but there are other means of implementing vaccination programs that will increase access and uptake.

One alternative to implementing school-based mandates is expanding the National Immunization Grant Program, which provides municipalities with federal money through the CDC to provide vaccines to citizens that are too wealthy to qualify for Medicaid and its Vaccines for Children program, but too poor to afford private health insurance (11). Additionally, public education programs may increase uptake simply by making more parents aware of the vaccine and how it may benefit their daughter. Eight states have already implemented legislation designed to educate the public about the HPV vaccine with the goal of increasing vaccine uptake (12). Another alternative is implementing insurance mandates that require private insurers with beneficiaries in a particular state to cover the HPV vaccine either in part or in full, though this may present unforeseen costs and/or risks. A final alternative is for the state to purchase the vaccine directly at a lower negotiated price and provide it free to its citizens. As previously discussed, New Hampshire has already implemented a program of this sort that provides the vaccine to all girls between 11 and 18 years of age. New Hampshire has experienced
shortages in their vaccine supply since enacting this program, which suggests that a major
obstacle to high vaccine uptake is cost rather than unwillingness to receive the vaccine.
This implies that an opt-in approach may establish herd immunity against HPV if funding
is provided to help parents pay for the vaccine. If states can afford it, they should
certainly consider taking New Hampshire’s approach and providing the vaccine free to all
girls in the state, regardless of insurance status. It is yet to be seen what percentage
uptake New Hampshire will achieve through this voluntary program, but if herd
immunity can be established without a mandate that is morally desirable. The primary
danger of this approach is that it may drain the public health budget, diverting funding
away from providing children with other, more important vaccines, as well as from other
important public health measures.

If states decide to mandate the HPV vaccine for girls entering sixth grade, it is
imperative that they include specific language in the legislation that allows parents to opt
out of the HPV vaccine for any reason due to its unique nature. This approach, which
was taken by the District of Columbia and Virginia, attempt to achieve the greatest public
health protection possible while maintaining some respect for parental authority. Having
an opt-out, rather than an opt-in, maximizes access to and uptake of vaccine, thereby
protecting public health to the maximum potential, yet still manages to respect autonomy.
Autonomy is intact because the opt-out is available; it is not unduly burdensome to ask a
parent to simply say ‘No.’ It would be important, however, to ensure that parents were
actually given the chance to say no and that the logistics of implementation did not make
it unduly burdensome for parents to opt-out of the vaccine. However, there are several
concerns about the broad opt-outs that DC and VA included in their HPV vaccine
mandates. First, opt-outs could weaken over time, making it harder for parents to refuse the HPV vaccine for their daughter. Second, states could fail to provide funding for the mandate, causing some students to be kept out of school or opt-out if their parents couldn’t afford the vaccine, regardless of their true opinions or desires regarding HPV vaccination. Finally, the extremely broad opt-out language included in the HPV vaccine mandate could open the door for other vaccine mandates to be loosened, which would endanger public health and be morally reproachable.

If the primary motivation for a mandate is to increase public access to and uptake of the HPV vaccine, it is prudent to wait a few years to see how high uptake gets without a mandate because the primary goal of any public health intervention should be to lower morbidity and mortality from disease, and if that can be done through less coercive means, that would be morally desirable since it would encourage social justice and strengthen citizens’ autonomy. The vaccine is currently available to the public through private physicians and is also covered by the Vaccines for Children program, which provides vaccines to children who qualify for Medicaid, are uninsured, or underinsured. This weakens the argument that the vaccine should be mandated to increase access since it’s already accessible for almost all children. One study found that 80% of American parents surveyed would consent to having their daughters vaccinated, which indicates that morbidity and mortality of cervical cancer could be significantly reduced through a voluntary vaccination program (16). While this is promising, uptake among the recommended age group is currently at about 50% for the first dose, and a substantial number of those that get the first dose also get the second and third doses of the vaccine (9). Some ethicists argue that “mandatory public health policies can be ethically justified
(only) if voluntary methods have failed (and) no less coercive alternatives exist” (3, 17). More long-term evidence is required to demonstrate that voluntary measures have failed since the vaccine has only been on the market for five years. It is morally desirable to achieve high vaccine uptake and population protection voluntarily, but the problem is likely to remain that those most in need of the vaccine, most at risk of developing cervical cancer, and least likely to get annual Pap tests are also the hardest to reach with voluntary vaccination programs. Voluntary vaccination programs for the HPV vaccine are advantageous because they preserve autonomy to the greatest degree possible, but they are disadvantageous because they provide the least benefit to those populations most at risk. Despite this, it is not just to infringe upon the rights of a majority of citizens in order to encourage a vulnerable population to make a wise health decision. Educational programs aimed at those populations most at risk for cervical cancer could alleviate the health disparities in a less coercive manner than mandates and aid high-risk populations in accessing the vaccine through the Vaccine for Children program.

We must be careful with mandates. To infringe upon the autonomy of citizens for the sake of public health is a matter of great importance. The weightiness of mandates has been articulated well by Pellegrino and Thomasma: “Involuntary and coercive measures must be undertaken with a clear perception of the dangers they pose to a democratic society: loss of personal freedom to choose a lifestyle, dependence upon governments to define values and concepts of the good life, and the imposition of cultural homogeneity” (1). States should carefully consider the possibility of public backlash against mandating a vaccine that protects against an STI that is not transmissible in a school-room setting and pursue other options to increase HPV vaccine uptake and access
if possible. Voluntary vaccination programs and educational programs prioritize autonomy; mandatory vaccination programs prioritize an egalitarian understanding of distributive justice. Both can accomplish good, but voluntary vaccination programs and educational programs can accomplish a similar good of disease prevention, if to a lesser extent, as mandates, and voluntary programs do so in a less coercive manner that imposes lesser burdens on the public. For these reasons, alternative vaccination programs are morally preferable to mandates, and mandates are not the optimal legislative solution. Javitt et al, opposing HPV vaccine mandates in the *Journal of Law, Medicine, and Ethics* conclude, “the success of childhood vaccination programs makes them a tempting target for the addition of new vaccines that, while beneficial to public health, exceed the original justifications for the development of such programs and impose new financial burdens on both the government, private physicians, and ultimately, the public” (10).

These concerns are paramount. Not every single effective, safe vaccine should be incorporated into childhood vaccination programs without a thorough evaluation of what the vaccine contributes to public health and whether or not the potential benefits of the vaccine justify a mandate. Javitt et al are right to point out that the HPV vaccine is different from other, previously mandated vaccines. States should not divert funding from other vaccine programs in order to cover this vaccine, but states should consider mandating insurance coverage of the vaccine.. States can negotiate lower prices with the vaccine manufacturer than private physicians or citizens can, and it would be immoral for states to do nothing to make the vaccine more accessible to those at highest risk for development of cervical cancer through educational programs or state-funded entitlement programs like VFC. HPV vaccine is very controversial because although eliminating
cervical cancer is a worthwhile cause, a variety of issues come into play with the HPV vaccine that our nation’s public health officials have yet to encounter in any other vaccine, prompting a re-evaluation of the proper role of vaccine mandates. This thesis has evaluated what makes the HPV vaccine different from previously mandated vaccines, offering an analysis of the proposed HPV vaccine mandates and arguing that the vaccine does not provide sufficient public health benefit to justify overriding individual autonomy for the sake of the public good. Although the HPV vaccine confers prospective benefit in the form of prevention of HPV-derived cancers to those who receive it, there is not enough of a public health necessity to justify imposing the high financial and moral costs of vaccination on the public. Because the potential burdens of an HPV vaccine mandate can be minimized through alternative, voluntary vaccination programs that confer similar public health benefits as mandates without coercion, and because in the absence of a public health necessity, it is unfair and unjust to impose the burdens of a vaccine mandate on the public, HPV vaccine mandates are immoral.
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