

INOCULATION HESITATIONS: EFFORTS TO UNDERSTAND &  
OVERCOME THE PITFALLS OF HPV POLITICS

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## ABSTRACT

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Released for public use in the summer of 2006, Gardasil, America's first HPV vaccine, entered the hearts and minds of the American people without delay. With a growing base of awareness to the dangers and prevalence of HPV infection amongst the population, this novel prophylactic held the promise of saving lives. Yet, despite the proven efficacy and public health benefits, Gardasil became mired in controversy and faced public rejection. Ever since making a divisive first impression, HPV vaccines have failed to be effectively utilized. The goal of this thesis is to answer the question: Why are HPV vaccines so underutilized in the United States?

The first task is to understand how the vaccine was introduced to the American people and what perception this produced. Through an analysis of marketing and political strategies, the vaccine's cultural construction can be determined. The second task is to understand how vaccine initiatives have been installed and evaluated following public conceptualization. Finally, through these efforts I will propose my own ideal approach that synthesizes the material and properly contextualizes it.

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## Introduction

Nowadays, there is a lot of talk about vaccines. Well, one particular, highly anticipated vaccine. The ongoing coronavirus pandemic has significantly raised public awareness of matters relating to public health and the power of vaccines. While the delivery of a coronavirus vaccine promises to save lives and revitalize economies, there will be many obstacles it will face upon its release. The vaccine will raise concerns over access to healthcare, the economic interests associated with immunizations, and the appropriate role of governmental authority. These obstacles will inevitably complicate vaccine delivery and possess the capacity to impede public health efforts to save lives.

All of these obstacles have been witnessed before. When the Human Papillomavirus (HPV) vaccine was released in American markets, the efforts taken by pharmaceutical companies, governments, healthcare providers and the public resulted in national division and vaccine refusal. By analyzing the pitfalls faced by the HPV vaccine, relevant actors in the coronavirus pandemic can identify how to best deliver the new prophylactic and save lives.

This thesis seeks to answer the question of why the HPV vaccine is so underutilized in the United States. I was first drawn to this topic in my sophomore year of college when I had a summer internship at MD Anderson Cancer Center. In my time there, I worked with the Head & Neck surgery staff and was surprised by the frequency that subjects of HPV and HPV vaccines arose. I remember the doctor that I was working with telling me that the majority of the cancer patients that he was treating were there because of HPV. He thought it was absurd that despite the fact that there was a vaccine that could protect against these cancers, nobody seemed to be using it appropriately. He bemoaned the notion that patients would continue to die from a preventable disease. If only parents utilized a vaccine with lifesaving potential for their children.

As a result of these experiences, I felt compelled to put my energy behind HPV vaccines. Immediately following my internship, I was motivated to pursue an initiative on college campuses to try and improve vaccine uptake. However, as I did more research on the vaccine, I was shocked to discover the fascinating and nuanced history that contributed to the lack of utilization. The story was not as straightforward as I had originally understood it. It was not simply a matter of there being a lifesaving vaccine that the population failed to use out of ignorance. Instead, the vaccine history was entangled in politics, economics, culture, and healthcare and was rife with controversy. Never before had I been so enamored by pharmaceutical histories. It felt as though I was reading about the scandal of the century and human lives were on the line.

Trying to answer the question of why the HPV vaccine is so underutilized brought me through an analysis of the history of immunizations and public health efforts in America. While the HPV vaccine was recent in its controversy, many public health initiatives have been poorly received due to their reliance on government instituted compulsory policies. Anti-vaxx groups are particularly salient in the current political landscape yet vaccines have faced resistance ever since they have been ingrained in society. However, the controversies associated with the HPV vaccine were particularly fascinating. Gardasil was the first vaccine to appear in a public forum following the infamous *Lancet* article that (falsely) claimed a connection between the MMR vaccine and the development of autism (Wakefield et al., 1998). No other debate over vaccination had been sensationalized by media outlets and touched on so many avenues of social division. As one American policymaker noted when the vaccine first became available, it has come to “encapsulate so many issues that are at the core of politics and health policy right now” (“Cancer Vaccine Bills Stall”, 2007).

When recounting the American story of Gardasil, the first HPV vaccine, nearly all actors it encountered contributed to the resistance and division it generated. Pharmaceutical powerhouse and Gardasil manufacturer, Merck, as well as politicians, healthcare providers and a reactionary public all shared part of the blame for producing a culture of inoculation hesitation. In the years surrounding Gardasil's release, Merck undertook efforts to redefine and restructure the public understanding of HPV and their respective vaccine in order to increase the vaccine's profitability. These efforts entangled the HPV vaccine in a political debate that reshaped perceptions of immunization through the lens of social and cultural divisions. A divided public and healthcare system cultivated a culture of mistrust, resentment and rejection towards a prophylactic that possessed the potential to save lives.

This thesis tackles the question of American HPV vaccine use by detailing these events and analyzing their far-reaching effects. The thesis begins by briefly providing relevant background information. By exploring topics relating to the American history of vaccine reception, the human papillomavirus, and the HPV vaccine itself, the reader can be better prepared to navigate the related topics that are further discussed throughout the work. The second chapter focuses on the marketing strategies that Merck utilized to enhance the profitability of their vaccine. These efforts ultimately contributed to vaccine resistance by generating the perception that Gardasil was designed to benefit pharmaceutical wealth rather than public health. Chapter three proceeds by outlining the lobbying efforts that Merck pursued and the political and public consequences these actions had on vaccine use. By placing the new vaccine in a political arena, Gardasil assumed the role of a political tool that produced social and cultural divisions that were met with resistance. In chapter four, efforts to improve vaccination rates following the vaccine's political fallout are analyzed. Identifying strengths and weaknesses

of these programs allows for a recommendation on how to improve HPV vaccine uptake going forward. The thesis concludes with a synthesis of the issues discussed which is facilitated by focusing on the contextual relevance of the moment.

While the failure of a controversial vaccine may not be the scandal of the century, lives certainly are on the line. HPV is widespread throughout the population and infection has the potential to cause cancer. My hope for this thesis is to raise public awareness of these issues and perhaps offer some insight over the pitfalls of vaccine delivery. While vaccines undoubtedly possess the potential to save lives, there is no promise that they will be well received and appropriately used. As we are all anxiously waiting for a new, and much needed vaccine, it is critical to be aware of the difficult road we have travelled thus far so we can better prepare for the road ahead.

## Chapter 1

### Background: As a Matter of Fact, These Facts Matter

The primary focus of this chapter is to go over relevant information and provide the reader with a context for the issues that will be discussed. The chapter will begin with a brief overview of the history of vaccines in America to yield some insight into the infrastructure that the HPV vaccine emerged. It shall proceed by defining HPV as a virus in addition to providing some background on disease prevalence and the risks of infection. Finally, the chapter will provide a brief exploration of the HPV vaccine with particular attention to its creation, effectiveness, utilization, and shortcomings.

#### **Vaccine Histories:** *Push and Pushback*

Since all public health interventions involve inducing a change within a population, they act as cultural and social instruments. The history of vaccination efforts in the United States highlights the multifaceted implications that come with vaccination and compulsory immunization policies. To effectively discuss the cultural effects that HPV vaccines generated and their relative lack of utilization, it is important to take into account the social framework that they enter into.

Vaccines have generated controversy throughout their long history. When the British military made typhoid vaccination mandatory for its soldiers fighting in Africa during the Boer War, it was met with such intense resistance that soldiers protested by throwing shipments of vaccines into the sea (Davidson, 2017). This Boston Tea Party-esque moment culminated in the military standing down from their mandate and allowing typhoid vaccination to be optional. When given the option, 95% of deployed soldiers refused to be vaccinated. This decision resulted in the deaths of 9,000 British soldiers as a consequence of typhoid.

Vaccination requirements, like all compulsory health measures, represent an ethical dilemma because they involve an intrusion of individual autonomy. Despite this intrusion, Government mandates have consistently presented as the most effective form of ensuring coverage and improving public health (Colgrove, 2010). Over the history of immunizations in the United States, governmental efforts to ensure vaccination occurred over two eras. Both eras were defined by sweeping efforts immediately followed by immense pushback.

The first generation of governmental vaccine interventions arose towards the end of the nineteenth century in response to smallpox. Laws that were passed during this period typically applied to all members of the general population, adults and children alike. Failure to abide by these laws resulted in a variety of penalties for those who refused, including potential fines and the threat of imprisonment (Colgrove 2010). As public education began to take hold across the nation, the schoolhouse quickly became a hotspot for contagion. To protect youths against infection, school age mandates became a popular means of ensuring vaccine uptake. Massachusetts, a pioneer in the use of public health law and regulation, became the first to link school attendance to proof of immunization in 1855 (Duffy, 1978).

Many other states followed suit and in turn the incidence of smallpox was drastically reduced (Colgrove 2010). Despite the reduction of disease incidence over the years, the population began to rise in resistance to these policies. Perhaps one of the greatest pitfalls to immunizations is the consequence of being effective. When populations are protected over long periods, a subsequent lack of firsthand experience regarding the terrors of the disease follows. As a result, periods of disease reduction were met with a reluctance to comply with vaccine policies. With complacency came resistance in the form of court challenges over the use of compulsion. Lawsuits over vaccination mandates appeared twice in the U.S. Supreme Court (*Jacobson v.*

*Massachusetts*, 1905; *Zucht v. King*, 1922) and in both cases, the court gave affirmations for the constitutionality of compulsory vaccination laws.

While some considered these shifts towards mandated public health initiatives to be the result of a beneficent government, others viewed it as a dangerous trend towards accepting a coercive environment. As popular democracy increased through the Progressive Era, so too, did anti-vaccination activism (Colgrove 2010). Activists used the new ballot processes that came into effect during this era to challenge their states' laws, resulting in the repeal of mandatory school vaccination laws in several states.

A second era of government involvement with immunizations was initiated in response to a Center for Disease Control (CDC) initiative to eradicate measles in 1968 (Colgrove 2010). To support its eradication campaign, the CDC urged states to enact laws requiring school-aged mandates for the recently licensed measles vaccine. State compliance with the recommendation was rapid and thorough; many of the states introduced mandates for the other recommended vaccines. By 1974, forty states had laws that covered all or most of the recommended childhood immunizations (CDC, 1978).

These laws were very much a product of the Great Society era, a period defined by activist government (Colgrove 2010). During Lyndon B. Johnson's administration, approximately fifty pieces of legislation related to providing for the health of the population were passed. Medicaid and Medicare, enacted in 1965, were the signature products of this period and exemplified the notion of a beneficent government that was trying to be established. All of these initiatives represented a common impulse: an attempt to remedy health disparities using the tools of the administrative state.

Building off the efforts of this era, lawmakers have added more and more mandates for new vaccines as they have been licensed. Between 1985 and 2006, the number of vaccines recommended by the CDC for children and adolescents doubled from seven to fourteen, and states have made most of these newly recommended vaccines school requirements (Colgrove 2010). School-aged mandates have thus established themselves as the infrastructure that vaccination efforts are established through. While there has been little legal pushback in response to this rapid expansion, a result due to the presence of exemptions for religious and personal beliefs in these new laws, a strong modern-day anti vaccination movement has emerged.

While the expansion of vaccination mandates increased resistance to immunizations amongst the population, the birth of the modern anti-vaccination movement was a result of the 1998 paper written by Andrew Wakefield that falsely claimed that MMR vaccination was associated with the development of autism (Wakefield et al., 1998). This gave rise to the current “anti-vaxxer” movement that we continue to encounter today. The movement has been bolstered by celebrity endorsements as well. In 2007, Jenny McCarthy figure headed the movement after her announcing that her son’s autism was caused by the MMR vaccine (Hoffman, 2019). While it was determined in 2011 that the claims of the Wakefield paper were based on manipulated data and fraudulent research, the damage to the public perception of vaccinations had been done (Godlee et al., 2011). As a result of the increase in vaccine hesitancy, the protections that mass inoculations confer to a population (herd immunity) have been threatened. The reduction in vaccine compliance has resulted in the recurrence of Measles outbreaks throughout the nation, a disease that was presumed to be eliminated in 2000 (*Measles Explained*, n.d.).

Throughout their history in the United States, immunizations have caused members of the populous to resist the compulsory efforts. Despite these resistances, the use of immunizations has

taken hold throughout the nation. The American vaccine infrastructure that has been established focuses on the school as the site for instituting vaccination requirements for the population. While the incidence of vaccine-preventable-diseases has been greatly reduced in the United States through national vaccine uptake, the reduction of disease has reduced the salience of disease dangers and increased vaccine reluctance.

### **The Human Papillomavirus: *A Common Threat***

While there is an abundance of relevant information to explore when considering HPV, it is crucial to provide insight into what the virus really is. HPV stands for Human Papillomavirus. Human papillomavirus is defined as any viral DNA that produces papillomas—benign epithelial tumors that grow exophytically—amongst humans (*NCI Dictionary of Cancer Terms*, 2011). In other words, HPV is a disease that has the potential to cause warts amongst the infected human population.

Warts, and thus HPV, have a long-known history. The warts that the infection causes have been known of since ancient Greek and Roman civilizations (Bäfverstedt, 1967). While the physical characteristics of HPV infection are easily noticeable and have allowed for their identification, much of the recent understanding of the infection has occurred over the last century through the developments of modern medicine and virology.

As of now, there are over 130 different types of discovered HPVs in the world (Davidson, 2017). These virus types, which are named/numbered by their order of discovery, are all closely genetically related. Definitionally, each virus type possesses less than a 10% difference in their DNA makeup (Aronowitz, 2010). The similarity in viral genetics also communicates a similarity amongst these viruses' means of transmission. All HPV viruses infect human skin and mucous membranes and are transmitted through physical contact (*HPV Infection*

- *Symptoms and Causes*, n.d.). While HPVs possess the potential to cause the manifestation of warts in infected individuals, many HPV infections present with little to no symptoms and resolve naturally.

Of the many HPV virus types, about sixty produce warts on the hands, fingers, and face (Aronowitz, 2010). This subset of HPV types is relatively common and generally amount to little more than cosmetic concerns and discomfort. Amongst this subset are the common plantar warts that can be contracted in public showers. While these infections represent the majority of the different HPV types, the collective understanding of HPV amongst the public differs.

Con conversationally, HPV generally refers to the 40 types of the virus that are transmitted via sexual contact. While the symptoms of potential wart production and the means of transmission through physical contact remain the same, the genital location and sexuality associated with the contact differ.

These sexually transmitted HPVs flourish in the soft wet tissues in the genital areas of both men and women. Transmission of these HPV types can occur through any form of contact with an infected epithelial cell. Due to the ubiquitous nature of sexual transmission, genital HPV infections are the most prevalent sexually transmitted infection (STI) in the world (Davidson, 2017). The CDC estimates that 79 million Americans are infected with HPV currently with somewhere between 6-14 million new infections occurring each year, the majority of which occur in people aged 15–24 (*STD Facts - Human Papillomavirus (HPV)*, 2019). The lifetime incidence of genital HPV infection in the United States is greater than 80% (*Fast Facts | HPV*, n.d.), essentially establishing that infection by some form of genital HPV is synonymous with being sexually active.

Efforts to measure the prevalence of HPV in populations have shown that infection occurs rapidly after the initiation of sexual activity. A study found that within two years of first reported vaginal intercourse, approximately 40% of the female population in the US had some form of genital HPV infection (Winer et al., 2008). While the lifetime incidence of the disease alone is striking, this finding establishes the immediate presence of risk in sexually active populations. The infection is present throughout populations and engaging in any type of sexual contact increases the risk of infection.

Unfortunately, the only true means of protection against contracting an HPV infection are through abstinence. While condoms offer a pathway towards reducing the risk of infection, they do not assure prevention. Condoms were found to reduce the risk of the HPV infections associated with genital warts, however they offered very limited protection against other genital HPV infections (Manhart & Koutsky, 2002). Considering the rampant prevalence of the infection and the lack of efficacy in safe sex measures, sexually active populations are faced with the possibility that contraction of HPVs are an inevitability.

Amongst laypeople, most HPV awareness is related to genital HPV infections that produce genital warts. This is likely because these are the clearest physical manifestations of an infection transmitted via sexual contact. Despite greater relative attention paid to these types of genital HPVs, only two of the forty HPV types are associated with genital warts (HPV 6 and 11) (Davidson, 2017). Infection by these virus types result in the growth of genital warts which tend to grow over the course of six months and then stabilize (Fairley & Donovan, 2010). While genital warts can be an extremely embarrassing problem, there are no long-term risks associated with infection. Infection by these virus types results in no more than cosmetic concerns. While

HPV infections cannot be cured, genital warts can be removed surgically—though this procedure tends to be expensive and wart recurrence is common (Davidson, 2017).

Determining the threat that HPVs pose to a population is rather complicated. Considering the sheer multitude of HPV virus types, most pose no health risks to the population. Very regularly, infected individuals never even become aware of the fact that they have been infected.

While most strains of HPV pose no health risk when contracted, a small number—roughly 15—of the virus types have been linked with cancers and are known to be carcinogenic (Davidson, 2017). These strains are known as “high-risk HPVs” and have been linked to cervical, vaginal, anal, penile, and oropharyngeal cancers. Out of all of the global cancers that are diagnosed on a yearly basis, 5% are caused by HPV infection (de Martel et al., 2012). The CDC estimates that about 34,800 HPV-associated cancers are newly diagnosed in the United States each year (CDC, 2020). Of these cancers, cervical cancer represents the majority of HPV associated cancers worldwide. In fact, 99.7% of cervical cancer cases are a result of HPV infection (Clifford et al., 2003). Of the 15 oncogenic high-risk HPV types, two are associated with the majority of HPV cancers. These two high risk strains are HPV 16 and HPV 18; they account for 70% of cervical cancers and 90% of all other HPV associated cancers (de Martel et al., 2012). Global estimates have found that, without preventative intervention, we will see 19 million cases of cervical cancer and 10 million deaths over the next 65 years (Bruni et al., 2016).

Cervical cancer used to be the leading cause of cancer death for women in the United States until the development of the Pap smear (NIH, 1996). This revolutionary method allowed for the detection and excision of precancerous cervical lesions. The death rate from cervical cancer has declined dramatically since 1955 (74% from 1955 to 1992) largely from the increased use of the Pap smear (McGraw & Ferrante, 2014). This success in reduction, though, has not

benefited all populations equally. Pap screenings are generally available only to populations that have access to quality health insurance—generally white and socioeconomically secure groups (Freeman HP & Wingrove BK, 2005). Pap screenings and the lack of access associated with them represents another iteration of the widening divide in health disparities.

The relative prevalence of cervical cancer versus male-associated HPV cancers has resulted in the public perception that HPV is a gendered disease. While the development of HPV-associated cancers occurs more rarely in men, infection rates of HPV in males and females are equal (McQuillan & Unger, 2017). While female populations are much more susceptible to developing HPV-associated cancers, it is important to note a recent trend developing in male populations. Occurrence of HPV-associated oropharyngeal cancers have increased by 225% in the United States over the past couple decades and have manifested primarily in male populations (Chaturvedi et al., 2011). Additional threats to male populations are HPV-associated anal cancers, which develop regularly in populations of men who have sex with men (Kim, 2010). A risk inherent to these cancers is the lack of preventative screenings available to detect for their precursors. Precursor lesions have yet to be identified for HPV-associated oropharyngeal cancers and, while anal Pap smears exist, they are rarely utilized (CDC, 2012). While Pap smears have been an effective tool in reducing female HPV-linked cancer deaths, no preventative parallel exists for affected males.

Though there have been immense advances in oncology, specifically relating to HPVs, much remains to be discovered. While it is known that HPV infection itself is a necessary condition for the development of some cancers, it is not sufficient (Braun & Phoun, 2010). HPV infection is a commonality; cervical cancer is a rarity. Furthermore, the high-risk types of HPV may not pose the extent of risk that would be expected with a title of high risk. Despite their

dangerous characterization, the vast majority of infections with HPV 16 and HPV 18 are transient and generally regress spontaneously without treatment within about two years (Schiffman et al., 2007). Despite these uncertainties, the evidence for a causal link between HPV and cervical cancer is tighter than almost any other causal association in cancer.

HPV is an extremely prevalent disease. While there are many virus types, and most are not a threat to public health, a small number that are sexually transmitted are linked to the development of cancers. HPV-linked cancers are associated with a large number of the world's cancers. Advances in medicine and virology have allowed for many of the characteristics of the virus to be identified but the extent of its relationship to the progression of cancer is yet to be determined.

#### **HPV Vaccines: *A Light at the End of the Tunnel***

Taking in the full scope of what HPV is and its associated risks can leave one feeling a bit uneasy. Infection seems an absolute certainty and the entire population appears at risk of developing cancers. Fortunately, a means of prevention was created: the HPV vaccine. Approved for use in 2006, an HPV vaccine entered the market and offered protection against 4 types of HPVs—the two highest risk carcinogenic strains (HPV 16 and 18) and the types most associated with genital warts (HPV 6 and 11) (Davidson, 2017). Preventing infection by these HPV types offered the promise of protection against HPV-associated cancers, especially cervical cancers. While pap screening, the only other means of preventing the progression of HPV-related cancers, had shown to be quite effective in reducing the rates of cervical cancers, the treatment was no more than a secondary means of prevention. The HPV vaccine offered a means of primary prevention, eliminating the initiating event and preventing HPV infection as a whole (Brotherton

et al., 2016). The vaccine additionally offered a means of protection to male populations, who were not able to benefit from HPV associated cancer screening technologies.

Today there are three distinct HPV vaccines that have been commercialized: Gardasil and Gardasil-9, made by the American pharmaceutical company Merck, and Cervarix, made by Britain's GlaxoSmithKline (Davidson, 2017). Cervarix is a bivalent vaccine that offers protection against HPV 16 and 18. Gardasil is a quadrivalent vaccine that offers protection against HPV 16, 18, 6, 11. Gardasil-9 represents the update to Merck's initial vaccine and includes protection against 9 HPV types. This nonavalent vaccine protects against the same four types that were in the original Gardasil vaccine, in addition to five other carcinogenic associated HPV types (HPV 31, 33, 45, 52, and 58).

All of these vaccines are administered as intramuscular injections. The vaccines have recently been made available to populations aged 9-45 for both male and females. Treatment involves the administration of three injections, with the second and third injection taking place one month and six months after the initial injection, respectively. In populations under 15, though, a two-dose administration has been approved. Younger populations still have developing immune systems and with just two injections separated by 6 months, lasting protection can be conferred.

The vaccine itself was a groundbreaking piece of medical technology that utilized innovative approaches of conferring immunity to HPV infection in treated populations. Researchers that sought to invent an effective vaccine found that by using molecular biology tricks, they were able to create something that resembled the virion by using just the protein that was most recognizable by antibodies. These artificial virions were called virus-like particles (VLP) and were able to generate extremely strong immune responses (Aronowitz, 2010). Most

other vaccines have relied on weakening the virus in some way and introducing it to the body (Colgrove, 2010). This approach, however, introduces the very risks that are associated with natural infection. By using only a single protein to generate VLP, HPV vaccines offered protection from infection without posing a risk amongst treated populations.

The drug appeared in clinical trials in 1999 and was fast-tracked for FDA approval in female populations in 2006 (Davidson, 2017). The trials were faced with a dilemma on both ethical and logistical grounds when determining how to measure the vaccine's efficacy. The vaccine aimed to prevent the development of cancers, yet the period from initial infection to cancer development was quite long (Lowy & Schiller, 2006). Additionally, the use of cancer—a life threatening disease—as a primary endpoint presented as a dangerous situation for patient populations. The efficacy data was thus based on whether or not immunized populations demonstrated protection against intermediate and high-grade cervical lesions. These lesions were defined as necessary precursors to cervical cancer development.

The data from these clinical efficacy trials showed promising results for these innovative vaccines. Both Cervarix and Gardasil gave 100 % protection for the most cancer-proximal endpoint while also providing strong protection against genital warts (Lehtinen et al., 2012). Additionally, the data showed that vaccination protected against the development of anal and vulvar vaginal lesions. However, data on the efficacy of HPV vaccines preventing penile and oropharyngeal cancers were limited due to difficulties in identifying premalignant lesions. In addition to displaying wonderful efficacy in clinical trials, the HPV vaccine has demonstrated stellar effectiveness in public use. A study on its effectiveness showed a 51% reduction in HPV16 and/or HPV18 2-3 years post-vaccination and a 73% reduction 4-6 years post-vaccine (Mesher et al., 2016). A recent study has demonstrated that by simply receiving one or two shots

of the vaccine, as opposed to the complete three-part series, treated populations will receive lifelong immunity (Safaeian et al., 2018).

A common worry amongst populations that resist vaccinations relates to concerns over the safety of vaccination. Studies that have tracked the results of HPV vaccinations have found that HPV vaccines have an excellent safety record (Macartney et al., 2013). While there are some complaints of low-grade and transient injection site reactions, these vaccines have no pattern of serious adverse effects.

While the HPV vaccine presents as a promising piece of biotechnology that stands to save millions of lives, there are some concerns that have been raised over its use. HPV vaccines protect against a number of HPV types but there is a worry that preventing infection by these virus types will only create a vacuum to be filled by other HPV types (Aronowitz, 2010). Vaccination aims to reduce the incidence of cervical cancers by a great magnitude but treatment could lead patients to discontinue regular Pap smears and miss the progression of other cancers. Considering that completing the HPV vaccine has an out of pocket cost of \$570, there is a fear that the HPV vaccine will only stand to further the socioeconomic divide that produces harmful healthcare disparities (Millikan, 2006).

Despite the potential drawbacks that come with vaccination, the HPV vaccine is undeniably a beneficial healthcare product. With their proven track record of safety and effectiveness, HPV vaccines have enormous potential for decreasing the burden of HPV-associated diseases in the world. In the 13 years that the vaccine has been available, it has been licensed for use in 82 countries, over 270 million doses have been administered, and an estimated 365,000 cases of cervical cancer and 150,000 deaths have been prevented- However, because protected individuals are never made aware of what dangers they could have faced,

these cases of prevention often go unnoticed and underappreciated. Despite these global successes, the vaccine has failed to be effectively utilized in the United States. Due to the divisions that were activated and ignited by the roll out of Gardasil, only 53% of girls and 44% of boys are up-to-date on their vaccination (Walker, 2017).

### **Conclusion**

Vaccines have a long and storied history in America. While their development has saved countless lives, efforts to increase utilization have commonly generated resistance from the population. Public health efforts require a little bit of coercion to maximize effectiveness, yet compulsory policies ignite debates over the intersection of governmental authority and individual liberty. The implementation of vaccine policies has established an infrastructure whereby vaccine requirements are incorporated into school attendance for children. The increase in vaccines required for children has given rise to a growing anti-vaccination movement that has popularized a resistance to immunizations.

Human Papillomaviruses are extremely common throughout the population. Of the many types that exist, a small subset is transmitted sexually and a smaller subset of these sexually transmitted viruses are carcinogenic. HPV is the most common STI in the world and is responsible for a considerable share of global cancers. Despite the widely held conception that HPV is a gendered disease, infection and progression to cancer occurs in both men and women. Considerable advances in virology and modern medicine has answered many of the questions relating to HPV yet much remains to be discovered.

The development of the HPV vaccine by Merck and GlaxoSmithKline offered the promise of protection and disease prevention. These vaccines have been approved for use in both male and female populations and have proven efficacy in clinical trials and effectiveness in the

field. While the vaccine has the potential to save lives, there are some concerns that its use may impede established preventative practices. Despite this, the vaccine offers an opportunity to prevent initial infection of a disease that has demonstrated a clear causal link to cancer.

By providing an overview of this relevant information, an exploration of the factors that have caused the HPV vaccine to be so underutilized in the United States can commence. With knowledge over the history of vaccines, the reader has an understanding of the existing vaccine infrastructure and the cultural context that surrounded Gardasil when it was released. Detailing the prevalence of HPV and the dangers of infection allows the reader to recognize the risky environment this virus has produced. Outlining relevant details pertaining to the HPV vaccine provides the reader with the opportunity to educate themselves on a vaccine that will be discussed extensively throughout this thesis. These details allow one to truly consider why the HPV vaccine has failed to be effectively utilized in America.

## Chapter 2

### Manufactured Necessity: Marketing Strategies and Profit Motives

Merck initiated its One Less campaign to promote their new Gardasil vaccine to American markets shortly after receiving FDA approval in 2006. The campaign featured a widely publicized television ad that featured a diverse, hip, cool group of young girls declaring that they would be One Less: One less case of HPV associated cervical cancer. An older woman then states, “Gardasil is the only vaccine that may help protect you against the four types of HPV that may cause 70% of cervical cancer,” and another (older) woman warns of side effects (Merck, 2006). The televised ad was designed to be cutting edge, yet it raised questions and concerns among viewers: Where was the urgency coming from? How concerned should one be over these potential side effects? Should one really buy fully into a vaccine that only *may* provide protection from four of the many HPV strains?

This chapter provides an analysis of how Merck approached marketing and selling their newly developed HPV vaccine, Gardasil. The marketing campaign undertaken by Merck highlighted key notions of how they sought to define the HPV vaccine culturally in America. They desired to present Gardasil as a *necessary* prophylactic for *young girls* that was *desexualized* to ensure and maximize their products’ *profitability*. These efforts, though, ultimately proved to be barriers towards uptake when the vaccine entered different social and political arenas. The sense of necessity that Merck sought to instill amongst the population was perceived to be manufactured for economic gain rather than a beneficent effort to increase awareness. By tailoring the vaccine for young girls, Merck ignited cultural divisions over gender dynamics. The submersion of the sexual components associated with HPV transmission was viewed as misleading and limited the public’s trust for Gardasil. Establishing profitability as

primary concern, Merck's high price for their vaccine and risk reduction focus impeded the acceptance of the product as a public good. Merck's efforts to define Gardasil amongst the American people proved to activate the various causes for concerns that were then translated into vocal criticisms and vaccine resistance. Merck stood to make billions off their vaccine, yet their capital focused presentation of Gardasil limited the efficacy of a beneficial healthcare product.

**A Perception of Necessity: *I Need It, I Want It***

The manner in which Gardasil presented their novel product to a public eye demonstrated how they wanted their vaccine to be perceived. The vaccine espoused a capacity to protect our young girls from the imminent danger that threatened them. Merck wanted Gardasil to be seen as the chivalrous knight in shining armor that could come to the desperate hand of the nation's distressed damsels. Yet Merck faced large hurdles to overcome if they were to establish a public sense of necessity for their innovative immunization. Firstly, the public was poorly educated on HPV and there was little common knowledge regarding what the infection was and the associated risks it possessed (Blake et al., 2015). Secondly, despite all that was known about HPVs and the associated risks of infection, there was not complete knowledge pertaining to the causal connection between HPV and the development of HPV associated cancers (Braun & Phoun, 2010). Finally, the majority of HPV cancers present as cervical cancer cases and while these deaths are common globally, preventative screenings through Pap smears have drastically reduced the risk of cervical cancer deaths in the US (McGraw & Ferrante, 2014). Merck faced a perilous fate in attempting to establish the need for their vaccine in American markets. They somehow had to sell a product to an uneducated market for a problem that already had capable treatment while lacking complete understanding of the problem they desired to remedy. While the naive public posed a challenge to accomplishing this task, it also allowed for Merck to

attempt a molding of public perception towards the most profitable interpretation of HPV and Gardasil. By selectively educating the population towards the risks associated with HPV, controversial issues relating to sexuality and gender could be submerged, allowing for an ideal perception of necessity to take hold. To accomplish this, though, they first had to raise awareness to the issue, or in other words, manufacture the public perception of fear.

Tantamount to Merck's success in selling Gardasil was increasing public awareness of the danger that HPV infection carried. This makes perfect sense upon simple inspection, after all, why would a population undergo an invasive procedure without adequate cause? Prior to the presence of the vaccine, HPVs were far removed from public knowledge. According to a 2000 survey, 70 percent of a sample of adults had not heard of HPV and 89 percent had never discussed the infection with a health care provider (Kaiser Family Foundation, 2000). Parents of girls coming of age in the mid 2000's, the vaccine's target demographic, were raised in a generation where sexual education classes did very little to educate their students on HPV. In an era where the majority of attention was paid to the HIV/AIDS epidemic, sexual education programs simply ignored HPVs or approached the infection in such narrow terms that efforts to educate on the subject had little learning value (Braun & Phoun, 2010).

The axiom "if you build it, they will come" does not always ring true. Regardless of how revolutionary an HPV vaccine was, if there was no market, the product would fail to be effectively utilized. Merck did not want to see Gardasil follow the path of other products where developers viewed their product as so innovative that they never stopped to answer the question of "who will buy this?"

Efforts to justify the necessity of emerging vaccine technologies are not novel to Gardasil. As it turns out, most newly created vaccines struggle with this due to the simple fact

that creating a *truly* necessary vaccine requires public consensus that they are treating a *truly* threatening disease. A necessary prophylactic is thus directed against a “specific, prevalent, serious, and communicable infectious disease” (Aronowitz, 2010, p. 22). Due to the successes of previous immunization efforts, potential targets for new vaccines tend to be less prevalent conditions that may already have other means of prevention and treatment. Put simply, developments of vaccine technologies were products of prioritization. Families in 19th century New York City could be expected to be far more concerned about the threat posed by a smallpox outbreak than contracting HPV. The diseases for which current vaccines are being developed were able to persist for so long in part due to the minimal threat they posed to the greater population. While HPV infection does in fact pose a legitimate threat to the population with its connection to cancers, the consequences of infection are experienced years later. As the consequences of HPV infection are neither soon, certain, nor salient, an HPV vaccine fails to generate the perception of necessity amongst the population.

An effort to remedy the limited understanding of HPV emerged in 2005, prior to FDA approval for Merck’s new product. A direct-to-consumer media promotion was launched as a non-branded awareness campaign called “Make the Connection” (Siers-Poisson, 2007). This campaign focused on raising public awareness about the etiological role of HPV in cervical cancer. In American markets, the awareness slogan “Tell Someone” encouraged girls to tell someone about the virus that causes cancer. These ads featured female celebrities— Latina actress America Ferrera; African-American actress Kimberly Elise; Caucasian actress Elisabeth Rohm—who wore bracelets and other campaign-related paraphernalia and discussed the threat that HPV posed (Redmond, 2011). Merck spent a reported \$107.3 million in advertising, including

\$841,000 for Internet ads on the human papillomavirus in addition to purchasing 295 TV advertisements in the quarter prior Gardasil's approval (Zimm & Bloom, 2006).

Merck's awareness campaign sought to communicate a simple notion: HPV is an omnipresent virus that causes cervical cancer. Their unbranded commercials portrayed women as fearful and shocked by learning that there was a connection between HPV and cancer. One such ad featured a woman blurting "Scary!" upon learning that a "common virus" causes cancer (Merck, 2005). Through these efforts, Merck established themselves as a concerned authority seeking to educate the public on a pressing public health issue. Yet, despite this well-to-do appearance, not much in terms of health education was actually communicated. The campaign did little to nothing to educate the masses on relevant information pertaining to the issue, including: not offering any explanation on what HPV is, providing no clarity on how this "common virus" is transmitted, and dismissing the notion that HPV can also be transmitted to and from men (Redmond, 2011). This awareness campaign communicated a message of fear and hopelessness to the people disguised as an effort towards public education.

The unbranded awareness campaigns that Merck hid behind to establish the need for a preventative prophylactic failed to incorporate true awareness into their awareness campaign. This lack of communication was not shortsighted, however, but was instead an effort by the pharmaceutical company to simplify and more firmly establish the narrative of necessity. Acknowledging the limitations in HPV knowledge, the associations with sexuality, and the existing yet limited understanding of HPV infection in men would hinder the message Merck sought to communicate. Merck was not looking to initiate a conversation over HPV, but was rather seeking to establish a sense that the public was living in a state of danger. By submerging

relevant details and masking the uncertainties surrounding HPV infection, Merck sought to communicate an exaggerated probability of developing cancer in its target markets.

Core to Merck's refusal to include health education efforts in their campaigns was an anxiety that doing so would make their product less palatable to a consumer public. While a causal pathway between cancer and HPV infection had been clearly established, the extent and nature of causality in this connection was largely unknown. Little was known as to why some HPV infections clear up and remain asymptomatic while others result in the development of cancers. Some cofactors—such as smoking, gender, and infection by another type of HPV—have been postulated to contribute to the likelihood of disease progression, though no mechanistic evidence was available to establish these possibilities (Braun & Phoun, 2010).

In addition to lacking a clearly defined and understood relationship between HPV and cancer, the “high-risk” HPVs that are delineated as the most dangerous forms of the virus may not be as risky as the title may lead one to believe. In fact, the vast majority of infections with HPV 16 and HPV 18 are short lived and generally regress spontaneously without treatment (Schiffman et al., 2007). This may come as a surprise to most readers, considering the label of “high-risk” tends to communicate the idea of a substantial and frightening probability of disease.

Acknowledging this lack of certainty and understanding of the causal connection between HPV and cancer would act to severely undermine Merck's efforts towards cultivating a public perception of necessity. If the public was made aware to the extent of unknowns surrounding the HPV/cancer connection, compliance and uptake could be severely limited. Merck thus attempted to erase the complexity associated with the issue by selectively educating in a relatively naive population.

After gaining FDA approval in 2006 for Gardasil, Merck aggressively marketed their product through their “One Less” campaign, sparing no expense. The campaign featured an interactive website, television commercials, and branded paraphernalia (Redmond, 2011). As discussed previously, these ads featured a diverse array of young women asserting the notion that through Gardasil, they could choose to be one less case of cervical cancer. Instead of communicating a sense of dread, like Merck’s previous awareness campaigns, the pharma giant offered a simple solution to the existing threat that they had primed within the population. However, these messages also refused to communicate relevant health information regarding HPVs.

Soon after FDA approval for Gardasil was granted, media outlets began pouring over the vaccine, featuring articles that made impressive claims of what the vaccine could do. An article in Time magazine stated that Gardasil was an “almost universally hailed ... medical triumph ... the first ever designed to prevent cancer” (Gibbs, 2006). The article goes on to state that cervical cancer was “the second most common cancer among women, and the third most deadly in the world.” The manner in which this statistic was framed falls in line with the ideology that Merck desired to sell, that cervical cancer is the third most lethal to women in the United States, a claim that is blatantly false (CDC, 2019). A content analysis of news articles from this period found that the type of general information (the transmission, symptoms, and prevalence of HPV) articulated in news coverage of the vaccine continued to be limited (Braun & Phoun, 2010).

While HPV vaccines offer an opportunity to confer immunity to a population from dangerous HPVs, it is important to remember that cervical cancer deaths are a relative rarity in the United States. Regular Pap smears allow for early detection and excision of precancerous lesions and HPV tests are available to determine if an individual should get checkups on a more

regular basis to prevent potential progression. All of these facts are absent in Merck's marketing message, a fact that generated significant pushback from the public. Their ad campaigns were designed to make cervical cancer appear as an impending and terrifying fate that could only be prevented through immunization. Dr. Samantha Gottlieb bemoans this fact in an interview, exclaiming "these ads create anxiety and fear when literally nothing in existing gynecological practice has changed!" (Garber, 2017).

The ads were designed to sell products by conjuring powerful emotional responses. Print ads that stated "She won't have to tell him she had HPV ... because she doesn't" capitalize on the presence of fear associated with the stigma of STIs and the feelings of worry, shame and confusion that are associated with them (Aronowitz, 2010, p. 21). While vaccination offers a powerful tool towards reducing the risk of HPV cancers and efforts to improve public awareness of their presence are important, marketing messages that obscure relevant information and heighten anxiety are more akin to fearmongering than educating.

Merck's marketing campaign was subjected to intense scrutiny for the affective approach they utilized. Despite the vitriol that arose from their initial campaign, Merck intensified the approach of guiltling and fearmongering when they released a 2016 ad for their updated vaccine, Gardasil-9, which was approved for use in both male and female populations. The new ad appeared in two different iterations, one featuring a young man and the other a young woman. Both are in their mid-twenties. Gottlieb (2018) describes the ads,

We see images and videos of the young adults from the past: as images and short video clips fade in and out, the narrator ages in reverse, while the older self, the man or woman, narrates his or her dismay that when he or she was a child, their parents didn't choose to vaccinate their child against HPV. As the man explains, "I was infected with HPV. Maybe my parents didn't know how widespread HPV is... Maybe they didn't know I would end up with cancer because of HPV. Maybe if they'd known there was a vaccine to help protect me when I was eleven or twelve. Maybe my parents just didn't know." A young child, presumably the narrator's past self, asks the camera directly, "Right, mom? Right, dad?" The ad ends with a simple orange screen and the words "What will you say?" read by an invisible female narrator who encourages parents not to wait, to talk to their children's doctor today. (p. 1)

While the threat of developing cancer from HPV infection is genuine, such an ad relies on conjuring an intense emotional response to be successful. The ad attempts to elicit strong affective responses of guilt, shame, and fear in parents while attempting to invoke a moral imperative within parents. “Right mom?”

The ad is reminiscent of perhaps the most infamous political ad to be broadcast on television: Lyndon B. Johnson’s 1964 presidential “Daisy Girl” ad. The ad opens on a girl plucking daisies in a meadow,

GIRL: One, two, three, four, five, seven, six, six, eight, nine...

MAN: Ten, nine, eight, seven, six, five, four, three, two, one, zero.

[Sound of Exploding Bomb]

LYNDON JOHNSON: These are the stakes: to make a world in which all of God’s children can live, are to go into the darkness. We must either love each other or we must die.

NARRATOR: Vote for President Johnson on November 3rd. The stakes are too high for you to stay home (Johnson, 1964).

Yes, perhaps the stakes are high when one considers the threat of HPV infection, just like how the stakes were high when voting for a President to determine Cold War foreign policy. Yet advertisements that raise the stakes to the nth degree to elicit the most intense of affective responses do not produce desirable effects. By instilling a sense of existential despair in their audiences, these ads in turn undermine their credibility while alienating viewers.

By engaging in efforts to overcome the deficits in public knowledge, Merck sought to redefine the public understanding of HPV and its connection to cervical cancer. While public awareness of HPV increased as a result of the awareness and marketing campaigns, so too did concern over Merck’s motivations. The sense of necessity that was core to Merck’s marketing campaign subsequently established a foundation of concern and distrust surrounding Gardasil’s reception.

### **A Gendered Drug: *Who Runs the World?***

Gardasil was released under the preface that it was a cervical cancer prevention prophylactic. Despite truly existing to prevent HPV infection, a risk present for both genders, Gardasil was designed as a women's health drug. While evidence of HPV associated cancers occurring in men had been present for 20 years prior to the release of the vaccine, Merck did not initially open Gardasil's market to boys. This notion may be puzzling at first, especially when considering that providing the vaccine to both boys and girls would double the size of the target market. No, gender dynamics were not at the core of this gendered approach, but rather limitations posed by evaluations standards. Despite the demonstrated relationship between HPV and the development of cancers in both genders, vaccine efficacy was difficult to prove in male populations. HPV cancers that developed in men lacked the easily identifiable precancerous lesions that occurred in cases of cervical cancer (CDC, 2012). Providing the vaccine for women primarily stemmed from a focus on efficiency, practicality and cost-effectiveness. Navigating FDA approval for a cervical cancer vaccine simply seemed to be a far simpler and rapid course to get the drug to market.

Though Merck's gendered approach for Gardasil was not grounded in sexism, it did reflect a societal trend in healthcare provision where products are feminized. By focusing on women to achieve the elimination of HPV, Merck demonstrated gender biases and heteronormative perspectives. Considering that Gardasil was approved for use in boys just three years after it was for girls, the impatience that Merck displayed furthers the notion that Merck was prioritizing their economic interests over the public health. Restricting HPV vaccine use to girls allowed for the vaccine to result in cultural divisions over gender roles and ultimately proved injurious towards vaccination efforts.

Feminization occurs when an issue's social construction concentrates on females (Douglas, 1998). When issues become feminized, the effects tend to result in a characterization of the issue as female focused with associated perceptions of power imbalances and vulnerability. These notions are particularly captivated by contraception. Displaying the associations tied to feminized products, Contraceptives are more costly for women (financially and physically), and women thus bear the burden of the procreative responsibility (Davis, 2017). Resultantly, contraceptives act to entrench a cultural and social understanding that men are not expected to bear responsibility in matters of sexual health (Oudshoorn, 2003).

Like contraception, HPV vaccines also aimed to reduce the potential of risky events that affect individuals irrespective of gender. Yet, also like contraceptives, HPV vaccines were presented as a woman's issue. Gardasil was a prophylactic for young girls designed to prevent the development of cervical cancer. Despite HPV infection and HPV associated cancers occurring in both genders, the burden of cost fell squarely on the shoulders of families who had young girls. A focus on cervical cancer placed women at the center of all HPV matters and they were subsequently expected to bear the burden of HPV reduction responsibilities.

Despite contributing to the unfortunate gender biases that exist in healthcare, the HPV vaccine initially targeted female populations as a result of the available science at the time. Historically, the relationship between HPV and cancer was established through the identification of cervical cancers (Epstein, 2010). This long history provided a sounder foundation of knowledge for Merck to build from when they sought to release their vaccine. While HPV associated cancers had been identified in men, there were no HPV cancers that were as prevalent and well understood as cervical cancers. Additionally, with a lack of identifiable endpoints for disease progression, any research in male populations would face difficulties in efforts to

appropriately measure treatment effects (CDC, 2012). The extent of the threat that HPV infection posed in populations irrespective of gender was limited by the scientific understanding at the time. As a result, HPV appeared as primarily a women's issue.

Public health experts have long understood that the fastest route towards the reduction and eradication of HPV infection at a population level would be through a universal vaccination program (Colgrove, 2010). If one was to utilize this understanding, boys and girls should both have been immunized, even if boys stood to gain little health benefits directly. A non-gender-based approach stood as a method to reduce the incidence of disease to a point where it did not pose a threat to the population. Vaccinating all children promised to spur the development of herd immunity in the most efficient manner. While this approach would benefit both boys and girls, pharmaceutical manufacturers of the vaccine faced a dilemma: selling parents on the notion that their young boys needed a cervical cancer vaccine. Unfortunately, altruism is not that good of a selling point. While companies could have attempted to brand the vaccine as a universal HPV cancer vaccine, HPV cancers in men were not sufficiently understood, and presented with incidence rates that simply seemed too low to justify mass inoculation (Polzer & Knabe, 2012).

In addition to opting for the gendered approach as a natural consequence of feasibility and circumstance, Gardasil utilized a gendered immunization strategy because of its purported cost-effectiveness. Currently, the availability of health care interventions considerably exceeds society's capacity to pay for them (Russell et al., 1996). Believing that herd immunity could be conferred to both males and females by ensuring HPV inoculation rates above 75% amongst women (Garnock-Jones & Giuliano, 2011), only vaccinating women was a way to reduce the costs associated with the provision of care. This line of thinking persisted for a considerable period even after Gardasil was approved for boys in 2009, as estimate models portrayed an

ungendered approach as medically unnecessary and financially irresponsible (Brisson et al., 2009).

By mistakenly framing the question and failing to incorporate relevant data, these models produced results that were inadvertently skewed. Approaching the immunization effort through a gender biased lens, advocates mistakenly framed the question as, “is it cost-effective to vaccinate both males and females compared to females only” rather than asking “is it cost-effective to vaccinate both genders compared to not vaccinating anyone at all?” No other immunization policy has relied on assessing the cost-effectiveness of a vaccine through gender-based herd immunity and such an approach has resulted in a failure to achieve adequate HPV vaccine uptake (Daley et al., 2017). Central to the models of cost-effectiveness that relied solely on treating women was an assumption of high female vaccine coverage. Unfortunately, the desired rate of 75% of American women completing the HPV vaccine series has never been achieved. As a consequence, both men and women were left vulnerable to the dangers of HPV infection.

Moreover, a gendered evaluation of herd immunity represented a strategy that was particularly vulnerable to penetrations. Attempting to achieve herd immunity by vaccinating half of the population allowed for straight men who were not vaccinated to pose a risk to unvaccinated female populations. Even if adequate inoculation rates were present amongst American females, the global environment is sufficiently dynamic enough that traveling American men and women stood to encounter greater risk when appearing in foreign nations where HPV vaccination was less common.

An additional limitation to the gendered herd immunity thesis was demonstrated by the approach’s predication on heteronormative worldviews. The initial logic of the HPV vaccine and herd immunity was dependent on an assumption that HPV transmission occurred strictly through

heterosexual practices. In direct contrast to this, HPV-associated cancers occur at a higher rate in men who have sex with men (MSM) than in other straight male populations. In fact, the incidence of HPV-linked anal cancer among MSM is higher than the incidence of cervical cancer among women (Dietz & Nyberg, 2011). Fortunately, HPV vaccination has proven to reduce the incidence of HPV-associated anal carcinomas considerably. However, the lack of vaccine recommendation and availability in male populations signaled a disregard and callousness towards the lives of a historically oppressed group. By gendering HPV prophylactics, MSM populations—a population that was particularly vulnerable to the consequences of HPV infection—faced a greater hurdle towards accessing much needed care. The assumption of heterosexual HPV transmission ignored MSM groups and contributed to the erasure of a particularly vulnerable population in healthcare practices.

The historical association of HPV existing as a gendered disease has contributed to the HPV vaccine's feminization, an association that has consequences for both men and women. Due to this gendered understanding, men have been found to be significantly less likely than women to know about HPV, the HPV vaccine, and the relationship between the virus and cancers (Blake et al., 2015). This paradigm has produced ignorant male populations that are particularly vulnerable to the dangers of HPV infection. Additionally, it has contributed to the risk experienced by unvaccinated female populations.

The cultural construction of HPV and its vaccine has contributed to placing an unnecessary burden of responsibility on women. Through feminizing HPV and its associated prophylactic, long-held beliefs about female responsibility for reproductive healthcare in heterosexual partnerships have been reinforced (de Melo-Martín, 2006). Concomitantly, feminization delineated the stigma and blame toward women as both the hosts and transmitting

agents of HPV (Westbrook & Fourie, 2015). Thus, females are tasked with bearing the burdens associated with HPV-related diseases while males fail to accurately gauge their risk of infection. As a result, parents of boys consistently underutilize the HPV vaccine demonstrated by the disparity in national vaccine completion rates between boys and girls, 44.3% and 53.1%, respectively (Walker, 2017).

Poor vaccination rates amongst men has proven to be consequential towards HPV related health outcomes in male populations. Oropharyngeal cancer incidence has increased by 225% in the past thirty years and 70 to 90 percent of these cancers are thought to be HPV associated (Osazuwa-Peters et al., 2017). Approximately 75% of HPV-associated oropharyngeal cancer patients are male and the disease is projected to surpass cervical cancer as the most common HPV-linked cancer in the United States by 2020 (Chaturvedi et al., 2011). The dangers of HPV infection pose a tangible threat to male populations. The gendered brand that Merck sought to attribute to Gardasil has proven to exacerbate these dangers by reducing vaccine delivery to male populations.

The decision to target female populations with a cervical cancer fighting drug was based primarily on the existing knowledge of the relationship between HPV and cancer. While this method represented a more practical and cost-effective approach for Merck, it was not without limitations. By gendering the vaccine, Gardasil became a feminized product that carried with it cultural connotations. The gendered dynamic established by an initially female-branded prophylactic has cultivated a persistent gender disparity in immunization.

### **Sexuality Dynamics: *A Not So Sexy Vaccine***

Sex makes things complicated. It has the capacity to make things that may seem simple and straightforward out to be more difficult for the parties involved: messier and lost behind the

veil of ambiguity. These complicating elements, unfortunately, can also be seen spilling over into the realm of healthcare, specifically manifesting with the HPV vaccine.

Many advertisers have relied on incorporating sexuality to boost their products' sales. However, matters of sexuality that manifest in the provision of healthcare have regularly resulted in the stigmatization, politicization, and misrepresentation of beneficial products and practices (Polzer & Knabe, 2012). Considering that Merck's HPV vaccine would be used as a treatment amongst adolescent girls, the inherent sexuality tethered to HPV transmission appeared as a barrier towards vaccine uptake. Merck identified this fact and considered HPV's association with female sexuality as problematic and capable of reducing Gardasil's profitability. To assuage this possibility, they attempted to present the infection and vaccine in a desexualized context, an effort thought to enhance the perception of necessity and reduce the risk of entanglement in sexual politics (Braun & Phoun, 2010). However, by completely submerging the sexual nature of the virus, Merck appeared as attempting to mislead and manipulate public perception for their own economic benefit.

Many previous healthcare treatments associated with sexual health have faced backlash upon their release and integration into practice. Cultural anxieties about female sexuality led to critiques of gynecological efforts to introduce routine pelvic exams for adolescent girls. These efforts of the 1940's and 1950's were considered extremely controversial, particularly amongst white and middle-class patient populations (Prescott, 2010). Opponents of the initiative thought that exams would threaten the modesty that was so foundational to the adolescent female identity. The result was division amongst the public and an enduring struggle to incorporate these exams into routine practices. To avoid the potential of a similar fate, Merck presented their efforts towards educating an HPV naive public in a desexualized context.

In addition to attempting to avoid the pitfalls faced by previous sexualized products, part of the desexualization effort was rooted in a desire to further establish the public perception of necessity for vaccine uptake. Merck made an effort to present HPV as an infection that people simply “got” (Redmond, 2011). In this context, HPV infection would no longer be viewed as a contracted STD but merely as a product of existing within an HPV-prevalent environment, thus representing the virus as more akin to the common cold than other venereal diseases. These endeavors contributed to the cultivation of a risky environment, where HPV was ubiquitous and infection was right around the corner.

Despite the naivety of the public, cervical cancer has long been seen as the natural consequence of women engaging in promiscuous behavior. Ever since the disease was observed at higher rates amongst married women than nuns, the disease carried with it a moral and social judgement over what an acceptable expression of female sexuality looks like (Braun & Phoun, 2010). However, amongst much of the scientific community there was a concerted effort to deny this line of thinking. Instead, scientists attempted to shift the perception of cervical cancer to an objective medical issue that carried no inherent judgement of devious behavior. While being interviewed, Anna Giuliano, a scientist at the H. Lee Moffit Cancer Center and Research Institute, explained that cervical cancer is “not about promiscuity” (Grady, 2007). In fact, she went on to state that “the more we can get that out of people’s minds, the faster we’ll be able to get prevention efforts out there.” While this opinion was premised on a motivation to reduce persistent sexist biases in medicine, ignoring and obscuring the sexual nature of HPV infection was misleading.

While it may not be the responsibility of a pharmaceutical company to educate the public on the connection between HPV and sex, by refusing to do so fortifies predominant

misconceptions of sexual health. A strategy of desexualizing Gardasil perpetuates a culture that lacks awareness of healthy sexuality and reduces the provision of quality health care (Chesler & Kessler, 2010). This refusal to acknowledge generated movements that sought to reclaim the lost female sexuality. An author amongst one of these collectives stated, “The discussion of HPV in the mainstream media is largely dominated by information from large pharmaceutical companies who currently focus their marketing on cervical cancer; we think this focus on making money instead of providing good health care for everyone is fucked up.” (Down There Health Collective, 2007). This refusal to acknowledge the role of sexuality has contributed to misconceptions amongst the public over the protection that HPV vaccination confers and molded women as invisible sexual agents (Braun & Phoun, 2010). Assuaging the inherent sexuality of HPV infection additionally reinforces a culture that discourages women from taking ownership of their sexual health and perpetuates a stigma of female sexual expression.

The sexualization of public health interventions has historically posed as a limitation for success. Desiring the maximization of product utilization and profits, Merck sought to avoid any potential entanglements in sexual politics when bringing Gardasil to market. This refusal prevented Merck from defining the relationship between sexuality and their vaccine and allowed the public to determine an appropriate reaction. By limiting the information communicated in their marketing and awareness campaigns, Merck reinforced misconceptions of sexual health and contributed to a naive and reactionary culture.

**Economic Motivations:** *Cash Rules Everything Around Me*

Essential to all of Merck’s marketing and branding efforts was a desire to maximize profitability for their product. A vaccine that was necessary, desexualized and gendered was regarded as the most profitable brand for Merck to ascribe to Gardasil. While vaccines were not

always seen as a cash cow in the pharmaceutical industry, developments in biotechnology and the pharmaceutical landscape allowed for Gardasil to carry a high price point. Merck's branding of Gardasil as a risk reduction therapy and the vaccine's high cost limited access to the prophylactic. By prioritizing profits over people, Merck came to be viewed as an avaricious actor and alienated Gardasil's customer base.

Gardasil does indeed present as an extremely beneficial piece of health technology, possessing the capability to prevent dangerous infections in at-risk populations. In addition to holding the promise of delivering quality care, the vaccine also held the promise of delivering quality cash. Through a sole reliance on a direct-to-consumer (DTC) marketing strategy, the vaccine was estimated to generate a whopping \$4.3 billion in revenue by 2010, just 4 years after its release (Silverman, 2005). Ever since the release of the Hepatitis B vaccine, pharmaceutical companies disregarded vaccine conceptions of old and instead perceived them as huge money-making opportunities. However, the economic potential associated with vaccines was still relatively novel at the time of Gardasil's release and the high cost of immunization contributed to pushback by the public (Lam, 2015). Gardasil incited questions over how much power should be entrusted to big pharma by toeing the line between taking advantage of in-need populations and providing a public good.

While vaccine prices have been rising for years, Gardasil stands out as a particularly expensive vaccine. Initially, the vaccine entered the market priced at a high cost of \$120 per shot or \$360 for the complete inoculation series, making it one of the most expensive vaccines in the US (Redmond, 2011). Currently, Merck's updated vaccine, Gardasil-9, has a complete three dose out of pocket cost of \$570 or more (Fay, 2019). These amounts are considerably higher than the costs of other common childhood vaccines (measles, mumps, and rubella, around \$35;

chickenpox, \$58) (Silverman, 2005). While most health insurance providers—both public and private—supply the vaccine to clients free of charge, Gardasil’s high cost has generated both immense capital and considerable concerns over reduced accessibility.

Selling at such a high cost communicated Merck’s desire to sell Gardasil to a particular market, a market that noticeably did not demonstrate the most need for HPV infection prevention. With prices that far exceeded those of contemporary immunizations, the drug would not be affordable amongst populations that lacked the means to access quality healthcare. Merck was more content with letting Gardasil become the Apple of HPV vaccines; despite reducing the market through higher prices, a more expensive vaccine stood to be more profitable than a vaccine that was more affordable and accessible. Unfortunately, the market that Merck ignored, poor and disadvantaged communities, was excluded from the distribution of a helpful healthcare technology despite demonstrating a higher incidence of death from HPV-associated infections and a lack of access to other preventive treatments. For those that could not afford to get recommended Pap smears as a result of inadequate healthcare, Gardasil and its therapeutic effects were luxuries beyond their economic reach.

Instead of producing a prototypical vaccine, whose primary purpose was to eliminate the burden of disease in the population and benefit public health, Gardasil catered more to individuals as a risk reduction therapy. Gardasil entered the pharmaceutical market at a period when treating risk was the dominant approach. Representative of this paradigm were products that prioritized individual focuses and utilized DTC marketing, products like Statins and Humulin (Aronowitz, 2010). Risk reducing drugs definitionally promise to “eliminate or control the fears, discomfort, and hassles associated with risk” (Aronowitz, 2010, p. 28). Principal to this strategy was the fact that it was the experience of risk itself, not just the objective, specific

dangers of disease, that such drugs aimed to reduce. Unlike other therapies, the market for risk-reducing drugs was limitless and the duration of use could be a lifetime. This fact allowed for risk-reducing drugs to generate massive capital in the pharmaceutical industry. Merck utilized a similar approach in its marketing campaign by branding their product as a means towards reducing the experiences of risk associated with HPV infection—particularly the negative and emotional experiences of STI stigma. In many ways, Gardasil existed primarily as a risk reduction vaccine that prioritized profitability over patient outcomes.

Not all vaccines possess this economic power. In fact, until recently, vaccine production was not a particularly profitable business at all. “Historically vaccines were produced at a relatively low price and sold with a low profit margin. They were add-ons to other products—mostly drugs—that pharmaceutical manufacturers were producing,” explains Neal Halsey, professor of pediatric infectious diseases and international health at Johns Hopkins Bloomberg School of Public Health (Lam, 2015). “The people working in vaccines described themselves as the stepchild of others, and they had to fight hard for the resources to develop new vaccines.”

Vaccines failed to become profitable products during this period due to the wealth of competing products. Traditional vaccine development depended on utilizing biological materials, usually from tissues from living organisms, when manufacturing immunizations. Once the possibility of developing a vaccine had been demonstrated, different biological techniques utilizing different biological materials could be used to develop similarly effective products. This environment made vaccines technologies from this era particularly difficult to patent (Aronowitz, 2010). This produced a competitive environment that forced vaccine costs to stay low. Like the Hepatitis B vaccine, Gardasil was developed using innovative recombinant DNA technologies rather than biologicals. Since these technologies demonstrate high specificity in their production,

vaccines produced in this manner have an easy pathway to patent protection. Protecting the intellectual property of these vaccines through patents prevented the formation of competition and allowed for vaccine prices to remain high.

These shifts in biotechnology thus reduced market competition and allowed for products to dominate within their niche. While DTC risk-reduction-based marketing strategies allowed vaccines to generate unprecedented profits, the holy grail for vaccines was to attain a government mandate for immunization as a condition of attending school. The vaccine infrastructure in the United States was and is built upon state implemented school-aged immunization requirements as a condition of attendance (Colgrove, 2010). New vaccines that entered the market and demonstrated a sufficient capacity to reduce the incidence of disease were incorporated into this infrastructure through state legislation. Obtaining a mandate for a particular immunization secured an expansive market for the product in addition to ensuring the longevity of its utilization. Subsequently, securing the enactment of school mandates across the nation was the ultimate goal for Merck as it was the most definite path towards securing the bag.

While profits are always a concern for all major corporations, at the time of Gardasil's release it was a particularly pressing concern for Merck. Prior to the vaccine's release, Merck found itself in hot water when it was accused of concealing the risks of its pain medication Vioxx; as a result of civil litigation, the firm had been ordered to pay billions of dollars in damages (Colgrove, 2010). Fortunately, the projected economic potential of a highly-utilized HPV vaccine could rescue Merck from their dire financial straits. When Merck attempted to attain a mandate status for their vaccine, some joked that to Merck, HPV stood for "Help Pay for Vioxx" ("More Re," 2007). Merck had a vested interest in recovering from the Vioxx disaster and sought to establish Gardasil as their ticket to economic salvation.

Merck's innovative prophylactic was developed in a moment that allowed for the immunization to generate unprecedented wealth in vaccine markets in addition to benefiting public health. Concomitant to this moment was the growth of skepticism directed towards the economic and political power of pharmaceuticals. When Merck attempted to establish mandates for Gardasil, these tensions were ignited resulting in a negative public and political evaluation of Merck's profit-over-people approach. Understanding the financial context that Merck existed in upon Gardasil's release contributes to the perception that the vaccine was designed more to accomplish capital cultivation than population protection.

### **Conclusion**

Gardasil was the first HPV vaccine product to hit global markets, yet it faced barriers in demonstrating its necessity to populations. To effectively sell their product, Merck had to overcome: a lack of public knowledge relating to HPV; foundational gaps and limited science relating to HPV and its associated cancers; and the presence of a viable and capable substitute for their product. While a naive target market posed as a barrier, it also provided Merck with the opportunity to attempt manufacturing the ideal public regard towards HPV, its associated issues, and the perceived benefits of vaccination by controlling the content and character of their awareness and product campaigns. The result was a manipulated and limited message that toed the line between raising awareness and fearmongering. While this approach was perceived to be the most profitable, it was particularly vulnerable to scrutiny and allowed for a critical perception of the vaccine to take hold.

While the justification for initially focusing development efforts in females was predicated on scientific and cost-effective evaluations, such evaluations proved to be faulty and misguided. The female focus that Gardasil initially assumed resulted in the feminization of the

HPV vaccine and contributed to cultural divisions over gender dynamics. The feminization of the product has also contributed to a culture that assuages male responsibility in matters relating to their healthcare and places greater blame on females despite greater prevalence of infection in male populations. Additionally, the gendered approach has left men, particularly gay men, at a greater risk for contraction of the infection and subsequent development of HPV-related cancers. Efforts to gender the vaccine helped establish a social understanding of HPV vaccines through a gendered lens and contributed to inoculation hesitations.

Merck wanted to avoid similar pitfalls of previous healthcare products that addressed issues of sexual health when they brought Gardasil to market. Following in the footsteps of other scientific thinkers at the time, they presented their prophylactic in a desexualized context hoping to skirt potential entanglements in sexual politics. While this effort could be argued as a means to erasing sexist regards in healthcare, it also amounts to misleading public perception. When Merck faced greater scrutiny after seeking to attain a mandate for their vaccine, attempts to avoid entanglement in sexual politics proved futile. As a result, these efforts to desexualize were viewed to be manipulative and a product of greater interests in capital generation over the provision of care.

Understanding the financial context that Merck existed in upon Gardasil's release contributes to the perception that the vaccine was designed more to accomplish capital cultivation than population protection. Merck's innovative prophylactic was developed in a moment that allowed for the immunization to generate unprecedented wealth in vaccine markets in addition to benefiting public health. Concurrent to this moment was the growth of skepticism directed towards the economic and political power of pharmaceuticals. These tensions were

ignited when Merck attempted to establish mandates for Gardasil, resulting in a negative public and political evaluation of Merck's profit-over-people approach.

HPV vaccines demonstrate a profound capability to protect populations from an infection that has been linked to many of the world's cancers. Despite the protective potential, Gardasil faced barriers towards successful implementation due to a naive public to HPV. Merck determined that if the public were to view their product as necessary, desexualized and to benefit young girls then they could maximize profitability. Despite their efforts, the marketing approaches that Merck utilized activated many cultural tensions. Merck had raised concerns over the wealth in the pharmaceutical industry, the ulterior motives of corporations shaping public perception, the uncommunicated role of gender and sexuality in HPV and, more broadly, the existing divisions over conceptions of gender and sexuality in America. When Merck was caught lobbying for school-aged mandates for their vaccine, all of these factors were ignited. Negative perceptions from multiple parties resulted in the removal of the vaccine from a healthcare domain and into the divisive arena of politics. Alone, any of these efforts may have been acceptable, yet when one regards the full system, they help explain the extent of controversy associated with the vaccine. The marketing approach taken by Merck directly contributed to the sociopolitical controversy associated with the vaccine that has reduced its utilization. While the vaccine is in fact a public good, the manner that it was delivered to the public undermined its efficacy.

## Chapter 3

### A Political Vaccine: Cultural Consequences of Pharmaceutical Lobbying

In early February of 2007, while Texas legislators were deliberating a bill that would require HPV vaccination for school attendance, Governor Rick Perry made national news by preempting their decision:

Never before have we had an opportunity to prevent cancer with a simple vaccine. While I understand the concerns expressed by some, I stand firmly on the side of protecting life. The HPV vaccine does not promote sex, it protects women's health. In the past, young women who have abstained from sex until marriage have contracted HPV from their husbands and faced the difficult task of defeating cervical cancer. This vaccine prevents that from happening.

Providing the HPV vaccine doesn't promote sexual promiscuity any more than providing the Hepatitis B vaccine promotes drug use. If the medical community developed a vaccine for lung cancer, would the same critics oppose it claiming it would encourage smoking?

Finally, parents need to know that they have the final decision about whether or not their daughter is vaccinated. I am a strong believer in protecting parental rights, which is why this executive order allows them to opt out (Perry, 2007).

Perry's actions fell in direct opposition to the conservative base that had elected him, contradicting his standing role as a political, economic, and social conservative. Despite Perry's attempt to align this endorsement with his base, the effort backfired on Perry and Gardasil. Within two days, Texas legislators submitted a bill that rejected any HPV vaccine requirements in the state (KXAN.com, 2007). Within a month, the state legislature had overturned his order and Gardasil had become a symbol of cultural division.

Vaccines, more than perhaps any other medical technology, distill and highlight the relationships of trust and skepticism between the state and its citizens. The HPV vaccine was no exception, and wherever the vaccine went, so too did extensive debates regarding the appropriate role of governance and the troubling relationship between policy makers, big capital, sexuality, and social control.

This chapter details and analyzes the complex interplay that emerged after HPV vaccines entered the political sphere. The focus will begin by detailing the cultural moment that Gardasil emerged in through an analysis of how Gardasil resembled a different Merck vaccine, Recombivax HB for Hepatitis B Virus (HBV). It will follow with an investigation of the extensive lobbying campaign Merck utilized to enshrine their vaccine under the legitimacy of school age mandates. The chapter will proceed with an analysis of the varieties of skepticism that emerged when the policy was debated in a public and political forum. The chapter will conclude with an assessment of current HPV utilization and how the implementation of the vaccine shaped its acceptance.

**Cultural Context:** *Recombivax HB, Model Vaccine*

Merck engaged the public in awareness and marketing campaigns for their product by utilizing a DTC approach. While this technique was projected to generate billions in profit, incorporating Gardasil into the vaccine infrastructure would ensure continued and widespread use of the vaccine. Through legislation that mandated girls receive the HPV vaccine as a condition of attending school, Merck would establish a perpetual customer base that spanned the entire population. Identifying the success of a similar vaccine, Recombivax HB, Merck pursued a rapid course for bringing Gardasil before policymakers (Rothman & Rothman, 2009). Despite Gardasil and Recombivax's similarities, there were key differences between the two diseases, their respective vaccines, their implementation strategies, and the cultural contexts they emerged in. These differences captivated the barriers that Gardasil would encounter when it entered a political sphere and the difficulties it would face in achieving the widespread uptake of Recombivax.

When a new and promising vaccine became available, school mandates were seen as the customary choice for policy makers seeking to ensure vaccine use throughout the population. Mandates were the established, proven path towards increasing herd immunity and the American vaccine infrastructure had been built around it (Colgrove, 2010). When one considers the prevalence of HPV in the population and the direct connection that infection has with the development of cancers, a mandate seems like a logical option to protect the public health. Such a pathway was sure to generate controversy, though, just as previous vaccines did when they entered the realm for public debate. At the heart of these controversies are the twin threats of risk and coercion. These threats invoke fears about state power vis-à-vis the individual, parental rights, violations of children's bodies, liberty versus the common good, and the intrusive reach of science and medicine.

While controversy was to be assumed by Merck, at face value Gardasil very much resembled the HBV vaccine Recombivax HB. Recombivax was also a prophylactic designed by Merck and the vaccine had successfully been incorporated into the vaccine infrastructure of school mandates with little pushback. There were many similarities between the two vaccines. Hepatitis B infection, like HPV, is transmitted sexually and when untreated commonly progresses to liver cancer (Hepatitis B Foundation, 2020). The vaccines also both relied on similar biotechnologies by utilizing VLPs to confer immunity in treated populations (Aronowitz, 2010). Ever since Recombivax has been incorporated into vaccine mandate policies, it has been considered to be safe, effective, and has widely been utilized (USDHHS & CDC, 2019). Identifying the similarities, one may expect Gardasil to follow a similar path; Merck certainly did as it based its decision-making process on their HBV vaccine model (Dickerson et al., 2011).

Despite Gardasil and Recombivax's similarities, there were key differences between the two which stood as barriers to Gardasil achieving the widespread uptake of Recombivax. While Hepatitis B is also connected to sexual transmission, unlike HPV, it is not strictly an STI (Hepatitis B Foundation, 2020). This distinction conferred Recombivax with greater resilience to the entanglements of sexuality debates. While infection with both viruses can lead to the progression of cancers, they differ in the type of cancers that develop. Gardasil focused on preventing cervical cancer, a fact that made it much more susceptible to scrutiny over its gendered focus, while Recombivax protected against liver cancer, a disease with no gender associations. Gardasil was administered in adolescent populations while Recombivax was to be administered in young children, a period in life when the specters of puberty and sexuality were far less salient (Casper & Carpenter, 2008). Further differentiating the two was their cost. To complete the full regimen of immunization, Recombivax cost \$69.60 while Gardasil cost \$390.81 (Dickerson et al., 2011). The increased cost of Gardasil fostered perceptions that the vaccine was designed with profit motives that outweighed efforts for public protection. While the implementation of a mandate for any vaccine generates concern over governmental authority, Gardasil tread upon a number of social issues. The social issues that differentiated Recombivax and Gardasil would come to define the controversy of the HPV vaccine.

The differing rates that the vaccines entered the vaccine infrastructure contributed to concerns over Gardasil's safety and efficacy. Recombivax was slowly incorporated into vaccine practices by the government, a fact that allowed it to grow in public acceptance and utilization before it was forced on the population. The same cannot be said for Gardasil. From the moment that Merck's HPV vaccine finished clinical trials, the prophylactic was rapidly incorporated into the public and political scene. Gardasil had been fast tracked for FDA approval and only five

months after being approved for use, legislation had appeared to institute mandates for its use (Charo, 2007). Recombivax, on the other hand, was available and used for seven years prior to Massachusetts introducing Mandate legislation. Unlike Recombivax HB, the marketing strategy for Gardasil was focused more on rapid achievement of sales goals versus a targeted strategy toward states with the highest incidence rates of cervical cancer (Dickerson et al., 2011). However, without the benefit of a lengthy evaluation period, Gardasil was substantially disadvantaged to achieve adoption of school immunization mandates relative to the pace established by Recombivax HB. As a result of the rapid introduction to the political forum, Gardasil did not have time to become established with consumers as a safe and effective vaccine. By prioritizing profit over public health, Merck alienated the American people and damaged the reputation of a lifesaving vaccine.

While Merck may have hoped that Gardasil would follow the path of Recombivax, they failed to account for the cultural divide over sexual and health politics that had grown between 1986 and 2006 when the two vaccines were released. As Casper et Al. (2008) stated, “pharmaceuticals do not unfold against the political background when they become available,” instead they “interact with and alter the political and cultural landscape – (re)shaping the pharmaceutical’s life course in turn” (p. 896). The shifts in public perception over these two decades prevented Gardasil from following in Recombivax’s steps. Instead, it created a new path that interacted with the cultural and ideological landscapes of the moment. The landscape that Gardasil entered was not as receptive to a novel vaccine, particularly one that tread upon the cultural divides that were defining the nation.

In the time between the two vaccines’ release, public acceptance of public health measures had seen radical shifts. The period prior to Recombivax’s release saw a rapid growth in

public health efforts evidenced by the passing of Medicare and Medicaid. Between 1985 and 2006, the number of vaccines recommended by the CDC for children and adolescents doubled from seven to fourteen (Colgrove, 2010). As a result, the majority of states implemented these newly recommended vaccines as school requirements. While there was little legal pushback in response to this rapid expansion, a strong anti-vaccination movement had emerged.

Gardasil entered the political dialogue at a time when the anti-vaccination movement was growing in popularity. As the first major vaccine since concerns of a connection between Autism and the MMR vaccine were raised, Gardasil was faced with overcoming population wide vaccine hesitancy (Hussain et al., 2018.). Recombivax had never encountered such hurdles. Instead, it entered a landscape that had been shaped by the AIDS epidemic, a time where the perception of disease vulnerability was high amongst the public (CDC, 1986). As Colgrove (2006) argues, “because the benefit vaccination offers – the absence of disease – is a ‘negative’ or unapparent one, its risks, though rare, seem more salient... the invocation of a certain number of illnesses or deaths that did not occur has much less rhetorical force when placed against numbers of vaccine adverse events, even if the latter are very few” (p. 8). At the time of Gardasil’s release, diseases were not considered a dominant issue and concerns over vaccines had the potential to outweigh the benefits. Gardasil and Recombivax were similar in many ways. However, due to differences in their respective cultural contexts, Gardasil faced greater difficulties to achieving public acceptance.

Through Recombivax’s success, Merck believed that they possessed a model for Gardasil’s installment as a mandated vaccine. While there were many similarities between the two vaccines, they were not equatable. Differences in cost, association with gender and sexuality, speed of implementation, and cultural contexts all came to limit Gardasil’s reception.

Merck, still believing that Recombivax's incorporation into the vaccine infrastructure was sufficient evidence for Gardasil's success, sought to bring Gardasil before policymakers without delay. However, this decision ultimately proved to increase resistance to HPV vaccine mandates and damage the lasting reputation of the vaccine.

**Lobbying Efforts:** *Texas, Our Texas! All Hail the Mighty State!*

While debates over the implementation of an HPV vaccine policy played out all over the nation, the most significant scenes occurred in none other than Austin, Texas. At the Women-in-Government (WIG) Cervical Cancer Summit in 2005, Texas was singled out as a desired proving ground for a push to enact liberal HPV vaccination policies into state law (Gottlieb, 2018). However, this effort seemed to conflict with the prospects of success as the conservative legislature had already voiced resistance towards the HPV vaccine (Bustillos, 2016). Despite the potential barriers, Merck had well established lobbying connections in Texas that led them to believe such an effort was feasible. Seeking to enact a state vaccination policy in a conservative state, Merck aggressively lobbied for the implementation of mandates by petitioning Governor Perry and the bipartisan WIG organization for support. While Merck was successful in achieving the implementation of a vaccine mandate in Texas, Perry's executive order (RP65) subverted the legislative process and conflicted with the Texan spirit of individual autonomy. The policy faced immense resistance and when Merck's lobbying efforts were uncovered, the entire nation erupted in vitriol. Merck succeeded in making Texas Gardasil's proving ground, but the results were disastrous for the pharmaceutical company. The dramatics that played out in Texas shaped the national perception that Gardasil was a controversial vaccine that was to be met with resistance.

Prior to even achieving FDA approval for Gardasil, Merck had been looking for a route to bring HPV vaccine policies into effect across the nation. They identified WIG as an organization that could champion their efforts. WIG is a group that defines itself as a “non-profit, bipartisan organization of women state legislators providing leadership opportunities, networking, expert forums, and educational resources to address and resolve public policy issues” (Women in Government, 2011). Merck was a corporate sponsor of WIG from 2004 to 2006 (Siers-Poisson, 2007). In 2004, WIG launched its Challenge to Eliminate Cervical Cancer, directly overlapping with Merck’s Make the Connection awareness campaign. Through WIG, Merck helped fund the introduction of bills involving the mandated usage, education, or payment of HPV vaccine in more than 40 states in between the years of 2006 and 2007 (National Conference of State Legislatures, 2018). To accomplish such a task, Merck funded the assembly of policy making task forces that were instructed to draft legislation prior to Gardasil even receiving FDA approval. At WIG’s behest, Texas was singled out as the proving grounds for Gardasil. Thus, the Cervical Cancer Strategic Planning Initiative’s (CCSPI) Policy Work Group was formed in Austin. As Dan Bustillos, a former member of the committee, described (2011), the group as a conglomeration of “disparate stakeholders, health care professionals, grassroots activists, academics, cancer survivors, health economists and health policy wonks” (p. 7) that convened to prepare comprehensive policy recommendations on what Texas could and should do once Gardasil became available in a few months.

While the CCSPI was working to draft their policy proposal for Governor Perry, the HPV debate had already begun in the Texas legislature. By drafting and submitting legislation for the mandatory vaccination against HPV for middle school girls in Texas on November 14th 2006, Representative Jessica Farrar (D- Houston) officially began the legislative process in the Texas

House of Representatives (The Texas House of Representatives, 2007). Notably, the introduction of this bill occurred just five months after Gardasil had been approved by the FDA for use in the population. The reaction to the bill was divisive. Political conservatives, religious advocacy groups, and parental rights groups criticized the HPV vaccine on moral, religious, and even medical grounds while proponents of the bill championed the vaccine's protective capabilities. Critics also claimed that Gardasil was an untested drug rumored to have terrible side effects that also promoted promiscuity among young girls. While all of these claims have been discredited, they were sufficient to produce a grounded resistance to mandate policies.

On February 3rd, 2007, the *Houston Chronicle* front-page headline read: "PERRY ORDERS CANCER VIRUS VACCINE FOR YOUNG GIRLS: Texas is 1st state requiring ages 11 and 12 to guard against sexually passed infection" (Elliott & Ackerman, 2007, p.1). With RP65, Perry had stipulated that the Department of Health and Human Services move with all speed to implement a vaccination program. It also required the legislature to work on funding for the initiative. While the order included a lenient opt-out policy for parents with moral or ethical objections, Perry's decision to issue a mandate through executive order came as a surprise for nearly all parties involved. The order seemed to conflict with Perry's entire brand as a social, political, and economic conservative. Adding to the confusion, legislation on the issue was being debated on the House floor at the time of the order.

The confusion surrounding Perry's order was so substantial that it prompted a thorough investigation to determine the cause of the Governor's unusual behavior. When questioned, Governor Perry expressed his personal motivations for such a decision (Charles, 2007). He acknowledged that cancer has affected many in his family and that he would do everything he could to fight the disease. Perry's wife, Anita, a nurse and the daughter of a doctor, has been a

strong proponent of the order as well. While these personal reasons for issuing an executive order are very noble, they do not tell the full story. Further inspection of Perry's dealings prior to the order revealed a financial connection between Perry, his former chief of staff, WIG and Merck.

On September 10th, 2004, The Austin Chronicle reported that Mike Toomey, Perry's chief of staff, left the state capitol to become a lobbyist for Merck at a time when Merck was making substantial donations to both Rick Perry and WIG. In 2005, Toomey functioned as a powerful liaison between Merck; his friend and former boss, Rick Perry; and the influential WIG, which counted among their Texas contingent Toomey's former co-worker and his replacement as Perry's chief-of-staff: Dierdre Delisi. Dierdre's mother-in-law, the Texas state representative Dianne Delisi, was WIG's director in Texas and chaired the Texas House Public Health Committee. Rep. Delisi had also been a prominent fixture in WIG's 2005 Cervical Cancer Summit (delivering a keynote speech alongside Anita Perry, Rick Perry's wife) and had paved the way for the legislative push in Texas. At this summit, WIG decided to focus its considerable political force and money to single out a model state in which to pass HPV vaccine legislation. WIG leaders, including Rep. Delisi, chose Texas. A Texas open records law request showed that Perry had been meeting with Merck lobbyists (including Toomey) all through the Fall of 2006. One notable entry, highlighted in Peterson's February 22nd article on Chief of Staff Delisi's calendar shows that on October 16 she met with other Perry staffers for an "HPV Vaccine for Children Briefing"—the same day that Merck made a large donation to Perry (Bustillos, 2016, p. 9).

Fueled by revelations connecting Merck's apparent economic interests with the implementation of public policy, public outrage grew and resistance to the vaccine was validated. Critics of the executive order complained that any effort to vaccinate the public was delegitimized by the economic entanglements between Merck, WIG and Perry. The president of the ultraconservative Texas Eagle forum pronounced that this was a case of "'follow the money' if I've ever seen it" (Elliott & Ackerman, 2007).

The negative perceptions of these economic entanglements were further exacerbated by the disclosure that the CCSPI had not even recommended for the implementation of a mandate policy. Instead, they recommended a voluntary vaccine program focused on public education and budget reallocation that would make the vaccine freely available to the young and poor. Recounting the decision, Bustillos (2016) stated that "not only would this policy have a greater chance of adoption in Texas than a mandate (and therefore was more likely to lower rates of

cervical cancer), it was also more respectful of the Texan ethos and culture” (p.8). Perry had issued his executive order just two days after the CCSPI had delivered their policy recommendation. Bustillos continued by asserting that the policy recommendation was so extensive that Perry and his staff would not have had enough time to read it. A cynical view was assumed that Perry had anticipated his order would be dismantled and had hoped to blame the action on the policy committee all while lining his coffers. Without a policy committee to blame the order on, Perry had to bear the burden of responsibility for his failed executive order, though it was Gardasil that paid the true price.

The negative reactions to the lobbying scandal were so intense that Merck publicly aborted its campaign for mandatory vaccination. “We do not want any misperception about Merck's role to distract from the ultimate goal of fighting cervical cancer, so Merck has re-evaluated its approach at the state level and we will not lobby for school requirements for Gardasil,” explained Mary Elizabeth Blake who served as Senior Director of Public Affairs for Merck’s vaccine division (Childs, 2007). As a result of Merck’s lobbying pursuits, Gardasil had been stripped of its status as a beneficial pharmaceutical and had assumed the role as a divisive political symbol. Public health advocates who were proponents of mandate bills were subsequently faced with the burden of justifying Merck’s lobbying actions. Through the cultural divisions that the vaccine tread upon and the damaging perception of Merck’s lobbying, a variety of criticisms for the vaccine emerged amongst its opponents. Despite the efficacy that Gardasil displayed, its reputation and reception was forever mired in the controversy of its political roll out.

### **Varieties of Skepticism: *Cultural Divisions Embodied***

As the debate over HPV vaccine policies played out across the nation, resistance to the efforts were common. Alina Salganicoff, director of women's health policy at the Kaiser Family Foundation, it “encapsulates so many issues that are at the core of politics and health policy right now” (“Cancer Vaccine Bills Stall,” 2007). While pushback was common amongst the public, the reasons for resistance varied greatly. The diversity of responses and varieties of skepticism that emerged reveal the questions of governance that exist within the population. In each context that the vaccine emerged, it assumed the role of a political tool, opening new possibilities of governance and control while provoking the possibility of protest and backlash. All politics are local and different sects of the population gravitated towards different reasons for concern when Gardasil was presented as a possibility. Amongst the various arguments, common themes surrounding vaccine and public health politics emerged: concern over complying with perceived coercive efforts by governmental authorities; the special status of adolescent girls as a particularly heightened proxy for popular attitudes toward the state; and the routine questioning of expert claims when economic motivations may be a guiding force in political decision making. The debates that ensued over the public health measures captured divisions that existed amongst the population. While many opposed mandate policies, the different arguments that were chosen by varying sects of the population proved to further divide the nation. HPV vaccine policies from this moment failed to be implemented because they held a mirror to the preexisting cultural divisions within the nation.

As mandate policies were debated, a public divide over the view of government as a coercive or beneficent force was displayed. Accusing the City Council of racist paternalism, columnist Courtland Milloy (2007) wrote sarcastically that “only the most progressive and caring

elected city official— in this case, two nice white people— would propose a program to vaccinate against sexually transmitted disease in girls under 13 in a predominantly black school system. After all, if the girls’ parents can’t protect them – and, God knows, they can’t protect themselves— then somebody’s gotta do it” (p. B1). While the notion that trying to prevent girls from developing cervical cancer could be seen as a racist plot may seem far-fetched to some, at the core of Milloy’s argument is an existing divide amongst Americans regarding compulsory governmental actions. To those who supported a vaccine mandate, it promoted a vision of a beneficent government that acted as a super parent— providing resources for families when such resources may have initially been unattainable. To those who stood in opposition, though, such efforts were seen as the acts of a government overstepping its bounds while impinging on the respect of the familial unit. Debates that focused on these distinctions captured the divide that persists amongst the population over the desired role that government should fulfill.

Throughout the country, ambivalence towards governmental authority is deep-seated, hearkening back as a founding principle when the nation was first established. American attitudes towards Gardasil often reflect a robust suspicion of government, while concurrently capturing a strong sense of entitlement within the middle-class towards the resources the government provides. Thus, sentiments of “Who are you to tell me to vaccinate my child?” communicate a grounded resistance to paternalistic governmental efforts while simultaneously establishing a presumption of access to the institutional infrastructure that makes such a provision available.

Despite the infrastructure in place, access to healthcare resources like vaccines and preventative screenings are not equal throughout America. Throughout the country, the epidemiology of cervical cancer and STDs follows variations in “wealth, resources, medical

infrastructure, and social structures— state by state, and across regions within states” (Livingston et al., 2010, p. 235). The burden of cervical cancer and HPV infection is concentrated in poor, segregated neighborhoods, a pattern that has been proven consistently throughout the nation. A WIG report (2008) noted that in Michigan, for example, cervical cancer incidence for whites was nearly half what it was for African Americans and Latinas (6.6 per 100,000 versus 11.6 and 11.7, respectively). Unfortunately, these disparities were reproduced in mortality rates as well (1.9 per 100,000 for whites versus 4.2 per 100,000 for African Americans) (p. 43).

No one likes being told what to do. But by contesting the vaccine policies on grounds of resisting governmental authority, a position held by many white conservatives, a level of privilege is communicated. While cervical cancer does not pose the threat that it once did in many American communities, many continue to suffer from its effects. Access to preventative screenings are not a luxury held by all and denying vaccination efforts thus denies an opportunity to improve public health and safety throughout the population, particularly amongst those that are most affected.

In accordance with deliberations over HPV mandate policies, similar arguments played out while using young women and their sexuality as a proxy battleground. Proponents of a vaccine mandate argued that vaccination was the only way to ensure a woman’s safety while navigating dangerous sexual terrains. Ruby Bailey, a Michigan obstetrician-gynecologist, argued in a March 2007 article that “Your daughter may be a virgin when she goes on her honeymoon, but unless her husband was pristine, he may bring [HPV] to the marriage bed... [Without the vaccine] One has no ability to protect themselves from the virus” (p.1). While vaccination was a sure-fire way to protect the nation’s girls and mandates presented as an effective strategy, many remained skeptical of the government’s focus on protecting families and young girls. This

dispute played out most directly surrounding the controversial claims that the HPV vaccine would encourage adolescent girls to engage in “risk-free” sex. When the questions of vaccines were raised, Social conservatives complained “that vaccination could encourage adolescents to be more promiscuous” while others alleged that through such a mandate “parents’ authority over their daughter’s health care would be usurped” (Levine, 2007, C1).

The disputes over these disproven claims became so widespread and intense that Gardasil no longer operated as a vaccine in the public sphere, but rather as a vehicle for engaging the public in debates over positions of female sexuality. While the connection that HPV and Gardasil shared with sexuality had initially been skirted by Merck in their marketing campaigns, the issue now overshadowed most other aspects about the product. Perhaps such controversy was unavoidable with a product like Gardasil, though by taking a backseat role in defining the connection and educating the public, Merck was left to watch as the public made their prophylactic into a symbol of sexual and political division.

Skeptical positions were held by many, but the debates that emerged over the control of female sexuality highlighted the sexist ideologies that were present amongst the population. A similar story played out in terms of the Hillary Clinton run for president. Consider a hypothetical exchange:

“I don’t think I would vote for Hillary because of her hawkish tendencies and I don’t want America to be involved in a global conflict.”

“Yeah man, you’re totally right, we absolutely cannot have a female president.”

“Well that’s not really what we were talking about... but I guess it is what we’re talking about now.”

While skepticism over a proposed Gardasil mandate was appropriate, the positions that those in opposition assumed displayed the ugly cultural divisions that persisted through the public. While all parties that resisted vaccination did not hold sexist viewpoints, these divisive ideologies had vocal representation in the debate over Gardasil. The fetishized focus on girls' sexuality that played out across the country displayed a cultural divide over the paternalistic zeitgeist of controlling women's bodies.

Matters of sexuality and paternalism dominated much of the debate over mandate policies. However, additional positions of skepticism were held by those with cited concerns over the vaccine's efficacy and the financial incentives that mandates represented. The HPV vaccine had been publicly available for less than a year when the majority of mandate policies were being considered. While Gardasil's purported safety and efficacy now is supported by years of data, at the time, parents had justifiable concerns before adhering to a policy that had potential consequences of harming their children. The parents "as guardians of specific children living individual lives, wanted proof beyond the quick acceptance of public officials looking to do good by a large swath of their constituents" ("Lawmakers Rethinking How to Cure Cancer," 2007, C1).

Parents and politicians alike were placed in a difficult role of evaluating whether or not they determined the vaccine to be effective. To complicate matters further, at the time that political debates over Gardasil were active it was possible to find both unambiguously positive and negative claims about the vaccine's efficacy. Cosette Wheeler, a professor of genetics and obstetrics-gynecology in New Mexico, stated in an interview that "the vaccine is 100 percent effective against HPV types 16 and 18, which are responsible for the majority of the cancers" (Dietz, 2006, F5). Yet it seemed that for every claim that heralded the vaccine, there would be a

matching rejoinder. A columnist for the *Grand Rapids Press* claimed in May 2007 that “new data on the controversial HPV vaccine... have raised serious concerns about its efficacy” (“Vaccine Faces Scrutiny,” 2007, A3) Lacking consensus over the safety that a decision to vaccinate would entail, many parents opted to resist mandate policies to avoid the possibility of risk. Despite Merck's effort to brand their vaccine as a risk reducing pharmaceutical, the perceptions of risk associated with vaccine use outweighed the perceived risks of HPV.

As a new economic and public health product, Gardasil generated anxieties in many contexts about how the profit motive shaped the push to vaccinate. These anxieties were only exacerbated when revelations of Merck's lobbying and financial dealings with politicians came to light. While concerns raised over the products safety and efficacy were quickly dispelled by Merck, academic scientists, and public health specialists, the credibility of these dismissals were difficult to evaluate due to the economic interests of stakeholders. Subsequently, questions have been raised over the appropriate role of the pharmaceutical industry in the development of healthcare policy. Upon these revelations, Merck's advertising campaign slogans, such as “cervical cancer kills x women per year” and “your daughter could become one less life affected by cervical cancer” (Rothman & Rothman, 2009) appeared to be designed to promote fear rather than educate the public to the potential benefits of vaccination. While the presence of economic motivations does not necessarily negate the quality of a product, marketing claims must be carefully examined against factual data.

The lobbying practices that Merck engaged in to bring mandate policies to state governments was by no means novel. In fact, lobbying practices were customary amongst pharmaceutical companies and large corporations (Drutman, 2015). However regular these actions were, they were seldomly displayed for the entire nation to react to. The public display of

Merck's lobbying efforts cemented an understanding throughout the population that economic motivations were a legitimate factor in HPV vaccine delivery. As a result, the public struggled to determine if Gardasil was in fact a commodity for enhancing public health or instead a pharmaceutical cash cow. The possibility that both realities could exist concurrently produced a cognitive dissonance that left a lasting apprehension over the appropriate role of money in politics.

While there were a variety of reasons that caused the population to resist HPV vaccine policies, each and every one was a result of an ongoing cultural debate. By touching on cultural divisions relating to the limits of governmental authority, issues of gender/sexuality, and corporate influence in politics, Gardasil came to symbolize how parents aligned themselves over cultural boundaries. Through Gardasil, the decision to vaccinate your child was a political choice. Choosing Gardasil became synonymous with choosing sides in a cultural battle. As a result, legislation over mandate policies failed and the HPV vaccine remains divisive in the memory of many Americans.

### **Prospects Following Pitfalls: *Unmet Potential***

The efforts that Merck engaged in to bring Gardasil to the public impeded effective delivery of the vaccine. Merck generated distrust and resistance amongst the population by pursuing a marketing campaign that prioritized profits over patients. Utilizing an approach that sought to desexualize and gender Gardasil proved to activate cultural divisions and alienate Merck's customer base. The rapid delivery of Gardasil to a political arena further alienated consumers as it raised concerns over profit motivations and vaccine safety. Without an established foundation of safe utilization throughout the public, compulsory policies heightened parental anxieties concerning their children's safety. When Merck's lobbying efforts to quickly

enact school mandates were discovered, resistance to policies that came to represent a corrupt and coercive government was validated. While the public assumed many different positions in their vaccine refusal, there was growing consensus that Gardasil was indeed a controversial vaccine that merited hostility.

The effects of the pitfalls that Merck and Gardasil encountered have been enduring. Of the 40 states where HPV bills were introduced, only Virginia and the District of Columbia were able to pass laws mandating HPV vaccine for females entering the sixth grade, although both laws contained a liberal parental opt-out provision (Barraza et al., 2016). In the months and years that immediately followed the political efforts to bring Gardasil to America's girls, HPV vaccination rates failed to rise to an acceptable level to confer population protection. A 2010 survey of HPV vaccine utilization found that only 21% of women reported ever receiving the vaccine (Williams, 2013). As a result of this poor uptake, the U.S. Department of Health and Human Services (2010) established a goal to bring HPV vaccine rates up to 80% by the end of the decade as a part of their HealthyPeople 2020 initiative. Despite this ambitious target without mandate policies, the desired results have never been achieved.

Over the past decade, there have been numerous changes made to HPV vaccine practices as an effort to improve utilization rates amongst the population. Merck saw their vaccine approved for use in male populations and saw the expansion of age groups such that boys and girls between the ages 9-27 qualified for the vaccine. The vaccine is now a routine recommended immunization of persons aged 11–12 years and initiation of the series at an early age only requires two injections to complete the series (Davidson, 2017). The passing of the Affordable Care Act increased access for the vaccine as well, by requiring private health insurers to cover HPV and other ACIP-recommended vaccines in addition to prohibiting copays or deductibles

when vaccines are delivered by an in-network provider (Schuchat, 2015). The quality of the vaccine itself has also seen improvement with the release of Gardasil-9, Merck's updated vaccine that offered protection against five additional HPVs. Through the expansion of the qualifying population for treatment, the reduction of cost barriers, and the enhancement of vaccine coverage, access to the vaccine has been significantly improved.

Through these efforts, HPV vaccination rates have seen significant improvement. Yet, despite these reductions in barriers, the vaccine has continually underperformed and struggled to meet its goals. In the most recent measure of national immunization rates (Walker, 2017), coverage with  $\geq 1$  dose of HPV vaccine measured at 68.1%, and the percentage of adolescents up-to-date with the HPV vaccine series measured at 51.1%. While these rates show improvement in vaccine utilization throughout the population, half of the population still remains vulnerable to HPV and its cancers.

A commonly utilized excuse for the lack of HPV vaccine utilization cites the relative recency of the vaccine (Dickerson et al., 2011). However, such a narrative no longer remains valid as the vaccine has been available for more than a decade. Furthermore, a vaccine that emerged after Gardasil has seen greater utilization throughout the population. The Tdap vaccine, which became widely utilized after receiving ACIP recommendation in 2011, has an extremely high coverage rate of 87.6% (Reagan-Steiner et al., 2015). Therefore, it is critical for the understanding of the poor vaccination rates amongst the American population that this is not a problem due to recency. Instead, this is a result of the conflicts that played out in the American social and political realms.

The resistance that was demonstrated over Gardasil in the US has not been reproduced in other nations. Rather, many other nations have widely adopted HPV vaccines (Dempsey & Patel,

2010). As a result of the population adherence to vaccinations, there has been a drastic reduction in the incidence of HPV infection and its associated cancers in these nations. In Australia, where a national HPV vaccine program had been implemented, recently published data showed that 78.6% of girls and 72.9% of boys were vaccinated by the age of 15 (Caffrey, 2018). Notably, this program was introduced to Australia in the same year of American debates over Gardasil. Instead of seeking to immediately introduce a compulsory policy for its citizens, Australia opted for a voluntary vaccine program that increased consumer access and allowed for the vaccine to become slowly incorporated into their national immunization infrastructure (Walters, 2019). As a result of these efforts, Australia now reports the lowest rates of cervical cancer and has seen a 77% reduction in the incidence of HPV infection (Albeck-Ripka, 2018). This national differentiation contributes to the understanding that Merck's political pitfalls produced an environment where HPV vaccine uptake failed to become customary.

HPV vaccines continue to be poorly utilized in the United States despite efforts to reduce barriers. While improvements in access has increased vaccination rates, population goals have never been met and half of the nation remains vulnerable to infection. While some may attribute the lack of utilization to the vaccine's recency or an inherent quality to a controversial vaccine, these arguments hold little sway. Instead, the lack of immunization uptake is a uniquely American, HPV vaccine problem. The political and social consequences of the controversy surrounding Gardasil's introduction serves as a lasting limitation to the vaccine's efficacy in the US.

### **Conclusion**

Through Gardasil, Merck had developed a product that promised to drastically reduce the prevalence of a harmful and ubiquitous disease while generating billions of dollars in profits. As

the current American vaccine infrastructure utilizes school aged mandates as a means to ensure immunization uptake, Merck sought to incorporate their vaccine into routine American practices. Merck sought to enact legislation across the nation that would impose vaccine requirements for Gardasil amongst American, female adolescents. Due to their successful policy efforts with Recombivax, which shared many similar attributes to Gardasil, such a task seemed feasible. Despite the similarities between the two prophylactics, key differences in terms of price, product recency, and cultural contextualization would come to differentiate their public reception and political acceptance.

Using all means at their disposal, Merck carried out intense lobbying campaigns across the nation through a reliance on the bipartisan organization WIG. Seeking to achieve a statement victory for Gardasil, Merck put the majority of their efforts in Texas to secure the passage of a school aged mandate policy. The logic was if Texas could be secured, the rest of the nation would follow. Despite Perry issuing an executive order for mandates, the action ultimately failed as it subverted the legislative process. When Merck's lobbying efforts were displayed, it resulted in immense pushback to HPV legislation across the nation.

When Merck's lobbying campaign became public knowledge, HPV vaccination policies and Gardasil itself drew skepticism from a multitude of positions. Through the varieties of skepticism, Gardasil was no longer regarded as a simple vaccine. Instead, it adopted a role as a politically charged tool that displayed the political and cultural divisions amongst the population. Issues over the role of governance, sexuality and economic interests in politics were highlighted. Despite Merck's best efforts, HPV vaccination proved to be a galvanizing force that prevented the passage of meaningful legislation.

The result of these pitfalls in policy making was the enduring perception that the HPV vaccine was controversial. While there have been many efforts to overcome this perception over the past decade, the vaccine continues to underperform compared to peer prophylactics. This failure to adopt the vaccine has very real consequences for Americans. While cervical cancer does not result in as many deaths in America as it once did, HPV-linked cancers continue to kill a large number of people. HPV vaccines are a valuable resource that could act to reduce population risks, particularly amongst poor, minority, gay and male communities. Despite the benefits that such a vaccine proposes to confer to the population, the charged political history that is associated with HPV vaccination has proven to drastically impede its utilization.

While Gardasil's political history cannot be erased and the passage of any new HPV vaccine legislation appears unlikely, there has been considerable effort to improve its uptake amongst the public through vaccine initiatives. While most of these efforts have only been marginally successful, some have produced significant increases in HPV vaccine uptake. These successes demonstrate that the barriers to vaccination can be overcome but may prove to be difficult. Many of these initiatives seek to establish in the public mind that Gardasil is just like any other vaccine. It is not like any other vaccine, though. The possibility for this conception has been stripped from the vaccine as a result of the failures in its presentation. It is unique in its political history and its association with cultural complexities. Thus, efforts to improve HPV vaccine utilization must seek to overcome these conceptions.

## Chapter 4

### Efforts Against Inertia: Reshaping Immunization Initiatives

This thesis thus far has sought to answer the question of why the HPV vaccine is underutilized in the United States. It has done so by inspecting the product's marketing, political, and social history. The focus now shifts to answering the same question through an analysis of how initiatives to improve vaccination rates, performed after the sociopolitical pitfalls of the vaccine's implementation, have been conducted thus far. This analysis was facilitated by categorizing the initiatives' interventional focus as informational, behavioral and environmental. Additionally, an analysis of the existing issues in these arenas that contribute to the need for change was provided. Among these arenas, successes and failures within programs were identified in addition to limitations in their focus and evaluation. The chapter will conclude with a synthesis of the material and a recommendation on how HPV vaccine initiatives and their evaluations should be conducted going forward.

#### **Informational Interventions: *I Know What I Know***

Efforts to increase public knowledge were a common focus among many of the initiatives to improve HPV vaccination rates. These efforts focused on increasing understanding of the HPV virus itself, HPV-related diseases and/or the HPV vaccine. Information campaigns conducted thus far have sought to educate targeted populations on these issues in an effort to increase utilization of the vaccine. Of these campaigns, many resembled the awareness and marketing campaigns that Merck engaged in when Gardasil first came to market.

Just as when the vaccine first emerged, the public has continued to lack awareness of the disease, the threat it poses, and the prophylactic that protects against it. Data collected from a

national survey in 2014 found that 32% of Americans had not heard of HPV and its vaccine (Blake et al., 2015). The same survey found that 38% of Americans lack knowledge of HPV and its role in cervical cancer. Among the surveyed population, females and younger age groups had more knowledge of these issues. Contributing to this understanding, a 2019 JAMA Pediatrics study (Suk et al., 2019) found that more than 70% of U.S. adults were unaware that human papillomavirus (HPV) causes anal, penile, and oral cancers. While public knowledge of HPV related information has improved over time, just as its scientific understanding has as well, public education on these matters have not been effectively implemented. In most of the United States, fewer than half of high schools and only a fifth of middle schools teach all 16 topics recommended by the CDC as essential components of sexual health education (*NHPC Press Release*, 2019). Informational initiatives identified the lack of robust knowledge pertaining to HPV and its vaccines and sought to improve vaccination rates through educational campaigns.

Informational interventions that focused on improving public knowledge were successful but limited in their scope. Interventions in this capacity were conducted in both individualized and community-wide approaches. An individualized intervention in the United States targeted low-income parents and provided education on the HPV vaccine (Suryadevara et al., 2013) resulting in a 16% increase in vaccine completion when compared to pre-intervention rates (p.322). A community-wide media information campaign in the United States targeting adolescent boys (Cates et al., 2014) resulted in higher rates of HPV vaccination while the media campaign was underway when compared to a control community with no campaign (1.34 hazard ratio) (Table 2).

Informational approaches improved rates of vaccination and were financially feasible. Their success was limited, though, by the lack of sustained changes after the intervention was

completed. Such initiatives require indefinite maintenance to result in lasting improvements which suggests such an approach would not be sufficient when used alone. The reach of these programs was also a limitation to their success. While individualized campaigns were more effective proportionally, they lacked the scope of community-wide efforts. While vast reach is required of initiatives that seek to increase population level vaccine rates, complications emerge when one considers the greater level of diversity in a larger target population. Health communication programs and materials that succeed in making information relevant to their intended audience have proven to be more effective than those that do not (Kreuter & Wray, 2003). Accounting for the heterogeneity of the population, diversity acts to limit such a campaign's efficacy as differing segments of the population have varying levels of response to the presented information. Thus, it is difficult to identify any specific educational strategy that could be utilized on a broad level. This concept is furthered by the Fu et al. study (2014) that reviewed 33 educational interventions and reached the conclusion that no specific strategy merited unilateral recommendation.

**Behavioral Interventions:** *Pushing People to Change*

Informational interventions hoped to produce an increase in vaccine uptake by simply providing educational materials to the population, a very hands-off approach. Behavioral interventions, on the other hand, were much more involved and dealt directly with the parties involved. The majority of identified interventions focused on attempting to produce changes in vaccine behaviors by providing necessary skills to make such a decision. These initiatives focused on conducting an intervention within either patient or provider populations. Patient interventions focused on improving vaccine behavior by either providing decision support or reminders. Meanwhile, provider interventions provided training to physicians aimed at

improving clinical behaviors when providing a vaccine recommendation. As cooperation was needed by both parties to ensure the administration of vaccines, an optimization of the behaviors on both ends promised to improve vaccine use.

When considering the need for an intervention at the patient level, one must weigh the role of the parent in the decision-making process. While the adolescent is the patient in the case of HPV vaccination, only parents can provide consent to initiate immunization practices (English et al., 2008). Unfortunately, parental refusal is a common occurrence when it comes to the HPV vaccine. According to Anna Beavis, MD, MPH, a gynecologic oncologist fellow at Johns Hopkins University, one in 5 parents of adolescent sons and 1 in 10 parents of adolescent daughters refuse the vaccine (Caffrey, 2018). Common reasons for refusal include concern over vaccine safety, a perceived lack of necessity and a lack of knowledge (Beavis et al., 2018). Notably, concerns relating to promiscuity and sexuality were not listed amongst these reasons. This fact provides pushback to the notion that sexuality is considered to be the primary issue when it comes to a parent's refusal of the HPV vaccine.

Behavioral interventions that were conducted amongst patient populations showed some success, though they did not achieve desired results. Message framing studies (Gerend & Shepherd, 2012; Hopfer, 2012; Rickert et al., 2015) sought to determine if the manner that HPV and vaccine information was presented to patients impacted their choice to vaccinate. Studies that utilized this approach were largely unsuccessful. However, Hopfer's (2012) study identified that amongst college-aged populations, peer recommendations carried greater weight than expert recommendations. These studies mostly demonstrated an increase in intent amongst treated groups rather than an increase in vaccine behavior. Unlike message-framing interventions, studies that provided patients and their parents with reminders to vaccinate (Chao et al., 2015;

Kharbanda et al., 2011) proved to be successful in achieving behavior changes. By providing mail and text message reminders to schedule a routine immunization appointment, HPV vaccine utilization was significantly increased. The magnitude of this increase in vaccine behavior, though, was not on the order of the desired Healthy People 2020 goals.

The role of the physician in providing a recommendation for HPV vaccination is critical to increasing uptake. In fact, the single biggest barrier to increasing HPV vaccination is not receiving a health care provider's recommendation (Gilkey et al., 2016). Unfortunately, a large number of physicians do not provide a quality recommendation. Amongst the population of parents that did not vaccinate their children against HPV, 10 % of parents of girls and 17% of parents of boys identified the lack of a provider recommendation as the primary reason to not vaccinate (Beavis et al., 2018). Taking these statistics into account, it appears that physicians have failed to effectively perform their duties to ensure quality vaccination rates. The CDC outlines specific guidelines on how to perform a vaccine recommendation that utilizes a “presumptive approach” (*Talking with Parents about Vaccines for Infants* | CDC, 2019). In this method, the doctor makes an announcement that assumes parents are ready to vaccinate their children, versus a conversational style that engages parents in an open-ended discussion. A study conducted by Opel et al. (2015) determined that this approach maximized parental compliance in vaccine recommendation. By contrast, 16% of pediatricians and 24% of family physicians said they instead use a conversational style when bringing up the issue (Kempe et al., 2019; Figure 1). While rectifying this deficiency is imperative to improving the rates of HPV immunization, such an accomplishment requires an identification of the many difficulties that providers face while recommending vaccination.

Many doctors have vocalized anxiety over HPV vaccine recommendation (Allison et al., 2016). Due to the loaded history of the vaccine, many parents refuse the vaccine when it is offered. This anticipation of refusal has left some doctors concerned that recommending the vaccine would cause patients to seek care elsewhere (Gilkey et al., 2016). The anticipation of parental refusal may also cause providers to adjust their recommendation style. This scenario results in a self-perpetuating cycle. Kempe et al. (2019) described it as such, “the circular nature of provider anticipation of refusal or deferral potentially lead[s] to a weaker recommendation style and less persistence in responding to parental hesitancy” (p.7). The loaded history of HPV vaccines and the anticipation of parental refusal cause providers to treat the HPV vaccine differently than other vaccines. Parents that identify this difference subsequently view the HPV vaccine as an immunization that requires more thought—an immunization that is not to be expected. While the HPV vaccine is by no means just another vaccine, like other vaccines it possesses the potential to protect children from a life-threatening disease. The political pitfalls that Gardasil faced have conferred a lasting impression on healthcare providers that inhibit their capacity to save lives.

Studies that performed behavioral interventions at the provider level (Gilkey et al., 2014; Perkins et al., 2015) provided physicians with training on how to best navigate parental pushback and improve the quality of their recommendation. These interventions used a version of the Centers for Disease Control and Prevention–endorsed Assessment/Feedback/Incentive/Exchange (AFIX) approach. Perkins et al. (2015) compared HPV vaccination rates at clinics randomized to the AFIX approach versus control clinics and demonstrated a significant increase in HPV uptake, most impressively among boys. Gilkey et al. (2014) sought to determine the best means of delivery for applying AFIX training for physicians. By testing and comparing the results of an

in-person AFIX consultation, a webinar AFIX consultation, and a control group, it was determined that in person training resulted in the greatest improvement in vaccine uptake behavior, though webinars were effective as well. Both studies commented on the high level of acceptability of the intervention by key stakeholders.

Behavioral interventions at both the provider level and the patient level resulted in an increase in vaccine uptake, though these results were magnified when they were conducted concurrently. Two studies (Cassidy et al., 2014; Fiks et al., 2013) were identified that utilized such an approach and the findings indicated that a combined approach resulted in the highest rates of vaccination initiation and completion. By using a combined approach that utilized family-focused reminders coupled with clinician-focused reminders and education, the studies resulted in a significant increase in vaccine initiation compared to the control group. The authors of these studies also commented that the implementation of these programs was simple and that parents welcomed the information provided.

Behavioral interventions represent a tangible means of increasing vaccine behavior. Interventions that focused on the patient were low in cost though alone failed to generate much more than an increase in intent to vaccinate. This approach has considerable limitations considering that the effective delivery of patient reminders requires a maintenance of up to date patient information. Additionally, such an approach would require a sustained application of practices as patient populations graduate upon completing the vaccine series.

Interventions that were applied at the provider level, however, resulted in lasting changes after the intervention was applied. These interventions resulted in a significant increase in vaccine behavior, though they are limited by the scope that they can be applied at. Barriers to wide implementation of in-person interventions include time requirements for already busy

physicians in addition to requiring physician compliance and engagement. While in-person training resulted in the greatest increase in vaccine behaviors, webinars have the benefit of increasing the reach of providers who could participate. The American Academy of Pediatrics recently developed an app for physicians that seeks to overcome the limitations of in-person training (Korioth, 2018). The “HPV Vaccine: Same Way, Same Day” app is a module-based program that is engaging and allows physicians to complete the material on their own time. This app provides an interactive training program for physicians so they can hone their vaccine-recommendation skills. The app also provides insight on how physicians can communicate with a parent that vocalizes concern for the vaccine even when the proper recommendation technique has been utilized. By training doctors in skills like motivational interviewing, they can be best prepared to handle parental concern appropriately and increase vaccine uptake. The app is delivered in short modules and can be completed in a little more than 40 minutes. By synthesizing the beneficial aspects of in-person and webinar interventions, the app seeks to maximize provider training and increase vaccine behavior.

Both patient and provider based behavioral interventions increased HPV vaccine use. However, the greatest effects were observed when these approaches were used in conjunction with one another. While provider targeted interventions were more successful for vaccine series initiation, it was patient targeted interventions that were most successful for series completion. These results indicate that providers pose the greatest barrier to vaccine series initiation, while patient or family barriers are a greater hindrance to series completion. These findings indicate that behavioral interventions represent a tangible means of increasing vaccine behavior.

### **Environmental Interventions:** *Addressing the Landscape*

Of the initiatives studied, those that had the greatest reach were the ones that implemented interventions at the environmental level. These efforts sought to enact change by altering the social environment in order to facilitate vaccination. By introducing new vaccine opportunities for targeted communities, a greater proportion of the population was able to participate in vaccination. While the most effective efforts at this level involved participation of local and national governments, such initiatives did not meet the same level of success in the United States as they did in other countries. Most efforts in the US incorporated the use of school-based vaccine programs.

The need for governmental involvement in vaccine programs to achieve population level protection is well established (Colgrove, 2010). In the US, the existing vaccine infrastructure only has the means of implementing requirements at a state level through school attendance requirements. Due to the complicated sociopolitical history of the HPV vaccine, governmental implementation of such policies has proven largely unsuccessful. A recent exception to this, though, is the state of Rhode Island. In 2015, the Rhode Island Department of Health decided to require the vaccine for all seventh graders (National Conference of State Legislatures, 2018). To accomplish this task, the Department utilized their authority over public health matters to implement the requirement without legislative approval. As a result of this action, the most recent CDC National Immunization Survey for Teens (NIS-teen) (Hill, 2018) demonstrated that Rhode Island had the highest vaccination coverage rates for the completion of HPV vaccine series (2 or 3 doses) for both male and female adolescents 13-17 years of age (78.1%) in the nation. The survey showed that other jurisdictions with school entry requirements had high HPV vaccine coverage as well (DC 78%, Virginia 59%). The argument for the effectiveness of

governmental involvement is furthered when one considers Australia. Australia was the first country to institute a national HPV program and observed high completion rates at both 1 and 5 years after the program was implemented (77% and 70%, respectively) (Brotherton et al., 2008; 2013). Considering these data, governmental involvement proves to be the most effective means of increasing vaccine rates. However, successful implementation requires active participation and approval of policymakers and the public.

Since the majority of states in the US have not enacted vaccine requirements for the HPV vaccine, environmental interventions sought to implement their initiatives as close to the existing vaccine infrastructure as possible. This effort to operate within social expectations resulted in the utilization of school-based vaccine programs. Five studies that utilized a school-based program in participating American middle schools were identified: 4 offered the vaccine for free (Caskey et al., 2013; Gold et al., 2011; Kempe et al., 2012; Stubbs et al., 2014) and one billed to insurance (Daley et al., 2014). Of the free programs, the study conducted by Kempe et al. (2012) proved to be most effective and demonstrated an initiation rate similar to national averages (59%), a dramatic improvement over the pre-intervention rate of 5% (Table 2). However, none of the participants completed the vaccine series. The remaining programs did not find the same success as the first, however, as they all reported rates well below national averages. The Stubbs et al. study (2014) only resulted in initiation and completion rates of 6% and 4.8%, respectively (Table 2). These programs struggled primarily due to the lack of participation amongst the student population. The difficulties posed by acquiring parental consent resulted in an average participation rate of 2% through these remaining studies.

Two studies (Moore et al., 2010; Navarrete et al., 2014) sought to circumvent the challenges posed by acquiring parental consent by targeting university students in their

interventions. Both programs offered the vaccine free of charge and proved to increase both initiation and completion rates. The Navarrete et al. study (2014) was supported by the Merck patient assistance program and targeted underinsured students. The intervention was coupled with patient reminders and resulted in an 89% initiation and 48.3% completion rate (Table 1).

When environmental initiatives were implemented, they consistently reached the greatest number of participants. The most successful of these interventions achieved the highest vaccination rates out of all of the initiatives studied. However, the results of these approaches were not consistent. At their core these approaches were effective, at points more so than initiatives involving an informational or behavioral approach. Environmental interventions had the greatest overall cost, though they continued to be cost-effective and well-received amongst participants. While many of the school-based programs did not achieve desired initiation rates, the majority of participants that initiated the vaccine series completed it as well.

These programs were not without limitations, however. In school-based programs, researchers consistently faced significant barriers, including stipulations to vaccine administration and low participation rates. School-based programs have proven to be more consistently successful in international settings than domestically (Walling et al., 2016). The relative difference is likely a consequence of the vaccine infrastructure in the United States, where immunizations are connected with pediatric visits as opposed to school-based clinics. Without being established as a social norm, school-based programs struggled to overcome the perception of novelty and generate population participation. While the greater reach of environmental approaches is a strength of these programs, it also makes successful implementation more difficult. Successful school-based programs require active participation by teachers, students, and parents. By involving a greater number of actors, there is a greater chance

of encountering resistance amongst the target population. Without adequate community support, these programs fail to generate sufficient participation and become ineffective in achieving significant improvements in vaccination rates.

Initiatives to date have proven to be moderately successful though such successes rarely met national averages or goals. While there is a definite advantage to interventions that have a wide scope and seek to produce a change in vaccine behavior amongst the largest population, this advantage also acts as a limitation due to the heterogeneity of the population. One consistent deficiency in nearly all of the studies analyzed was the lack of data on race/ethnicity and socioeconomic status. This lack of data made it difficult to determine whether or not certain interventions proved to be more effective amongst different segments of the population. Given the significant disparity in outcomes of HPV related diseases, it is imperative to develop a better understanding of the relationship between demographics and vaccination behavior.

Without any knowledge of the characteristics of the treated audience, the reproducibility of successful interventions is limited. The effects of these initiatives are understood through a macro lens, where the target population is the general American populace and changes in immunization rates are measured at the national or state level (Rahman et al., 2014). The American people are not a generalizable group, however. The diversity of the nation and heterogeneity of its people would limit the efficacy of any nationwide initiative since different populations respond better to different methods. In fact, Lee & Garland have suggested that public health proposals to increase the uptake of the HPV vaccine within a population are most effective when tailored to a specific population (2017). By refocusing how initiatives are conducted and evaluated to be more attuned with the community they are implemented in, HPV vaccine utilization can be improved. Identifying the sociodemographic characteristics of

communities where interventions have been successful provides a pathway towards reproducibility and broader implementation.

**Regional Focuses:** *Macro to Micro*

Demographics related to HPV vaccination uptake can vary widely, even between adjacent counties within the same state (Hill, 2018). Most studies to date rely on data from the NIS-teen to determine the population efficacy of initiatives (Walker, 2017). Recently, enough data was collected in this survey to measure immunization rates in different counties within the state of Texas. By analyzing the variation in HPV vaccination rates within a state, a deeper understanding of the causality that demographic and community factors have on vaccine uptake can be cultivated.

A study by Conrey et al. (2020) compared data from Dallas County, El Paso County, Travis County, Bexar County, the City of Houston, and the rest of the state and found significant differences in rates of both initiation and completion of the HPV vaccination series. In fact, residence in Dallas County was a significant predictor of failing to initiate the HPV vaccine series. When adjusting for sociodemographic characteristics, which also varied significantly between the regions, residence in Dallas County continued to be a predictor in a lack of vaccine initiation. This indicates that a cultural factor that cannot be explained by sociodemographic data exists in Dallas County that contributes to vaccine behavior. El Paso County, on the other hand, demonstrated the highest rates of vaccine initiation and completion between the six regions. While the state of Texas had one of the lowest rates of HPV vaccination uptake in the nation, El Paso County had the fifth highest initiation rate and fourth highest completion rate of all the areas surveyed by the NIS-Teen in 2016 (Walker, 2017).

The relatively greater rates of vaccination in El Paso can potentially be explained by considering the characteristics associated with sociodemographic factors of the counties populous. As the region is situated on the US-Mexico border, a large number of the county's residents are Hispanic when compared to other regions in the state. Hispanic women in the US-Mexico border region are significantly more likely to be diagnosed with cervical cancer than non-Hispanic women (Coughlin et al., 2008). Considering these findings in conjunction with studies that have demonstrated a positive correlation between HPV vaccine uptake and perceived risk of HPV-related cancers provides a rationale for the greater rates of vaccine behavior in El Paso County. Additionally, El Paso County successfully implemented a culturally-tailored HPV vaccine campaign that improved vaccination rates across the county (Molokwu et al., 2019).

The success of the culturally-tailored HPV vaccine campaign in El Paso serves as a guide to optimize public health efforts that seek to improve vaccine utilization. This program utilized a multicomponent (education, navigation and access provision) culturally tailored and evidence-based HPV approach to measure the effects on actual vaccine completion rates in a predominantly low-income Hispanic community. In this study, efforts were taken to develop an understanding of the community before the implementation of the intervention. Focus groups were deployed to identify cultural concerns, barriers and knowledge gaps specific to the community. By engaging the population and identifying community specific needs, educational, navigational and provisional efforts were adapted to best fit the population the program was targeting. The intervention significantly improved HPV immunization rates in the community and represents an advancement in the administration of public health initiatives.

These data on regional vaccine use demonstrate that variation in HPV vaccination uptake occurs within differing regions of the same state. It is likely that if enough data were collected on

vaccination rates for all states to provide county specific data, similar findings would be demonstrated. The relationships portrayed through these data illustrate the importance of examining smaller, more homogeneous regions when developing public health interventions aimed at increasing vaccination uptake. By developing a cultural understanding of local regions and implementing interventions through that understanding, a greater proportion of the population may be protected from the development of life-threatening diseases.

### **Synthesis & Suggestions**

Numerous approaches have sought to improve HPV vaccination rates. By categorizing these efforts by their approach, patterns of success and failure can be identified. By examining and synthesizing the myriad interventions that sought to improve HPV vaccination uptake rates, an ideal intervention can be constructed.

Environmental approaches have demonstrated the greatest successes of the programs studied in this thesis. Environmental interventions are most successful when they are applied through governmental channels, but these channels have been stymied in the US. As the vaccine infrastructure in the United States is built upon individual states enacting school-aged mandates, the HPV vaccine's complicated political history has generally prevented the enactment of state mandates. Rhode Island's recent HPV policy goes against this, though, and may demonstrate changes in HPV vaccine's political narrative and increased public acceptance. Considering the extremely high rates of HPV vaccine completion in Rhode Island (78%), incorporation of state policies for mandates presents as the best avenue for achieving vaccination goals of 80%.

The average age of a new mother in the US is 26 (Bui & Miller, 2018). By this fact, these mothers were 13 years old when the political drama of Gardasil played out across the nation. As memories associated with the divisive roll out of HPV vaccine policies of the late 2000's fade,

the loaded history of HPV vaccination has less sway as a preventative measure on the enactment of HPV legislation. Thus, the fading memory of the cultural associations with HPV vaccines represents an opportunity to reshape the public perception of the prophylactic. This opportunity should be capitalized upon to prevent the vaccine from acting as a symbol of cultural division, and instead assume the role of another routine immunization. By accomplishing this task, the barriers to vaccine legislation can be dismantled and policies can successfully be enacted.

Until such a task is accomplished, though, environmental interventions must utilize school-based vaccine programs. While these programs have demonstrated success, the cultural novelty of such programs in the US and the requisite for broad community support limit these programs' efficacy. To bolster the successes of these programs, they should be conducted through local infrastructures to incorporate effective cultural knowledge of the targeted region.

While the memory of Gardasil's rollout may be beginning to fade amongst the American people, as of now many parents continue to refuse HPV vaccination for their children. When such events occur, the best strategic approach utilizes patient- and provider-focused behavioral interventions. Data has consistently demonstrated that provider recommendations are the strongest predictor of initiation of the HPV vaccine series. Many providers fail to effectively implement a strong recommendation for their patients by utilizing a presumptive approach and instead opt to initially engage in a dialogue with parents about the HPV vaccine. By doing so, physicians communicate that parents should not view the HPV vaccine equally as other recommended vaccines. While the HPV vaccine may not be the same as other vaccines, engaging parents in such a manner provokes anxieties that lead to vaccine refusal. With proper provider behavior, these parental anxieties can be assuaged and vaccine behavior can be increased.

Effective behavioral interventions for patients and providers involve training for physicians so as to improve initiation rates and reminder messages for parents to improve completion rates. While in-person training sessions for physicians have demonstrated the strongest effect on increasing vaccine uptake, such a program would be difficult to implement throughout the population. Webinars are a more cost-effective approach though they do not provide the same level of engagement that in-person training does. To synthesize the two approaches, the AAP has recently released an app called “HPV Vaccine: Same Way, Same Day.” The means of delivery for this training app allows physicians to engage with the content, is cost effective relative to national in person AFIX training, and provides physicians with the freedom to complete the course on their own time. An optimized behavioral intervention for providers and patients would implement this app as a requirement for physicians continuing education, supplemented with a short reflection to ensure provider engagement, coupled with patient reminders to improve chances of vaccine completion.

While informational interventions did not result in improvements in HPV vaccine uptake on an order of magnitude equal to environmental or behavioral approaches, they still are a promising way to engage the community on the issues relating to HPV. Efforts in this arena should focus on engaging populations through local infrastructure with cultural awareness and sensitivity. By operating through trusted, local figures and established institutional frameworks, these efforts will improve public knowledge. Additionally, such an approach may help instill a sense of trust amongst the community that the information and recommendations delivered to them are based on a desire to improve their health outcomes.

While perhaps a more difficult avenue to institute change, informational interventions that target sexual education courses taught to the nation’s youth could result in greater HPV

vaccine behavior. Considering that new mothers today were 13 at the time of Gardasil's release, increasing HPV specific knowledge for children today is a means to reduce parental vaccine refusal rates in the coming decades.

While evaluating immunization efforts at the nationwide level is critical to assess progress in achieving vaccination goals, macro-geographic evaluations fail to account for the sociodemographic characteristics of smaller communities that affect vaccine behavior. Initiatives that are executed on a more local scale are conducted through a less heterogeneous population and thus have fewer confounding variables that contribute to barriers to vaccine uptake. By examining the sociodemographic characteristics of a small region before making public health efforts to increase HPV vaccine uptake, barriers posed by cultural population dynamics can be reduced. By identifying communities that act to be representative of certain sociodemographic characteristics, a foundation for future interventions can be established.

Considering all of these evaluations, an optimal intervention requires a synthesis of all approaches. By operating through local infrastructures with an awareness of the cultural and sociodemographic characteristics that have shaped the community, initiatives can achieve a greater rate of success in improving HPV vaccine uptake. Environmental approaches that incorporate local awareness into their campaign have a greater chance for improving vaccine rates—though school-based programs may continue to face disparate success. Informational interventions that tailor their content to local population dynamics should be implemented broadly throughout the nation to improve public knowledge and generate patient trust and awareness. Behavioral interventions, too, should be maintained by implementing patient reminders when possible and requiring recommendation training for pediatricians and family

physicians. Through a multifaceted approach like this, the risk of a life-threatening infection can be reduced.

## Conclusion

In many ways, the history of the HPV vaccine in the United States captivates the history of American cultural and political ideologies. It captures the ongoing tension between governmental authority and individual liberty. It demonstrates the relationship between the American consumer, the government, and corporations. It illustrates the healthcare disparities experienced by many of the nation's disadvantaged groups. It portrays the complexities associated with navigating topics of gender and sexuality. The HPV vaccine was not inherently controversial, it simply held a mirror to the persisting divisions over American ideals. While the HPV story shows the consequences of failure, it also shows the hopeful promise of relentless perseverance.

There are many things to be learned through this analysis and now is a particularly pressing time to account for the lessons told by the HPV vaccine and its political and cultural associations. Vaccine politics and public health efforts are now more relevant than they have been in over 100 years. The coronavirus pandemic has reactivated many of the same debates around the world that were previously presented by the HPV vaccine. Gardasil proved to be a divisive piece of medical technology when it was first released. Inevitably, the new COVID-19 vaccine will activate similar divisions, though this time they will play out on the global stage. While divisions over gender and sexuality may not be as salient an issue for the eventual vaccine, many of the anxieties relating to healthcare disparities and governmental authority will dominate the conversation.

The completion of the coronavirus vaccine will subsequently initiate global conflict over access to the prophylactic. A primary concern that will need to be addressed is the decision of who will get first priority for the vaccine. The supply of vaccines will not be able to meet the

global demand and nations will compete amongst each other for a seat at the table. The interstate competitions that played out over ventilator access will be magnified on a global scale. Only through vaccination will a nation be able to protect its citizens and safely end the economic consequences of lockdowns. The citizens of developing nations, where the healthcare infrastructures are weak, are the most vulnerable to the pandemic. Despite this demonstrated need, developed nations will likely utilize their power on the global stage to provide for their citizens first.

The eventual costs for immunization further raise concerns of vaccine access. Pharmaceutical companies have been pouring an exorbitant amount of capital into developing the fastest-made vaccine in human history. The large investment by these actors will demand a large return. According to Dr. Peter Bach, director at the Center for Health Policy and Outcomes at the Memorial Sloan Kettering Cancer Center, “If we depend on the private market to develop a vaccine they will demand a very high return for success” (Buchwald, 2020). If this were to come to fruition, the coronavirus vaccine would highlight similar concerns as the HPV vaccine did over access to an expensive yet medically valuable drug. Poor citizens and poor nations will struggle to gain access to the vaccine in such a scenario and will inevitably suffer through the consequences.

In addition to activating similar concerns over access, the coronavirus vaccine will mimic Gardasil in its activation of resistance to a perceived coercive government. While it is yet to be determined if the coronavirus vaccine will be mandatory, resistance groups have already mounted a force against governments. Anti-vaxxers have been extremely vocal at protests in recent weeks and express extreme concerns that the eventual vaccine will be forced upon them.

Those rising up in resistance assert that they are trying to ensure their individual liberty and that this is ultimately about freedom (Bogel-Burroughs, 2020).

The coronavirus vaccine will be the fastest-developed vaccine in human history. The HPV vaccine was fast-tracked for FDA approval and brought before legislations for mandate consideration within 2 years of its release. With rapid initiation comes increased skepticism over matters of efficacy and safety. Populations across the world will express concern over the viability of the developed prophylactic and many will resist participation in global immunization efforts. While some governments might aim to overcome this by making vaccination compulsory, this will only exacerbate cultural divisions over respect for governmental authority.

It is critical to learn from the mistakes made by the HPV vaccine. When divisions were heightened by the HPV vaccine, the vaccine failed and so did the public. With coronavirus, the stakes are too high to let a similar story play out. The limited access over the vaccine will exacerbate global divisions between the haves and have-nots. Despite the limited access, there will be significant resistance amongst populations to the vaccine over fears of safety and ideals of liberty. To best limit the global damage that such a scenario would provoke, vaccine developers must ensure that the vaccine is affordable and governments must do their best to limit the perception that their vaccine policies are coercive. Access to the vaccine should be determined based on regions that demonstrate the greatest level of need as opposed to a system where health and safety is a right only afforded to the wealthy and well connected. While other nations may have the healthcare infrastructure to make coronavirus vaccination compulsory, such a policy would be damaging in the United States. This would give rise to a large anti-vaccination movement that could reduce uptake for other standard immunizations.

While there are many concerns raised by the eventual release of a coronavirus vaccine, there is room for hope. The coronavirus pandemic has resulted in increased concerns over public health safety throughout the global population and a greater awareness of the power that vaccines possess. While there will be resistance amongst certain sects of the population, the development of these vaccines will also likely increase public regard and acceptance for vaccine technologies. How this divide in the population is managed will determine the success of the American healthcare system for years to come. If the public consensus over vaccines is favorable, vaccine uptake may increase and the incidence of vaccine-preventable disease can be reduced.

Prior to the onset of the pandemic, America was facing a possible paradigm shift in its healthcare system. If the coronavirus vaccine rollout is effective and public participation follows, America may enter a new age of healthcare prosperity. The effort to eradicate polio gave rise to the adoption of Medicaid and Medicare, policies that drastically reduced barriers to healthcare access. The coronavirus pandemic has only acted to highlight the inefficiencies and vulnerabilities that the existing healthcare structure has, and there is cause to establish a new healthcare status quo for Americans where healthcare is a right afforded to all.

The coronavirus has, will and probably should dominate much of the global dialogue for an extended period. While this disease persists, so does HPV. By going through all the discussed material, it is clear that HPV is a dangerous disease that is extremely prevalent amongst the global population. Infection by the virus is well-established to be associated with the development of many life-threatening cancers that affect both men and women. The virus is so prevalent that most people in America will contract it at some point in their life if they engage in sexual behaviors. While secondary means of prevention like the Pap smear have reduced the mortality associated with cervical cancer in the US, preventative screenings do not exist for

many HPV-associated cancers. Additionally, the benefits of preventative screenings are not afforded to all, as there are numerous individuals in the global and national population that do not have adequate access to such procedures.

The HPV vaccine is and has been a safe and effective medical technology capable of drastically reducing the incidence of HPV infection and the development of HPV-associated cancers. Despite the promise the vaccine holds to eliminate an extremely prevalent threat to public health, it has faced barriers to its acceptance and incorporation into regular vaccine practices. Noting a lack of public knowledge regarding the threat of HPV and its associated cancers, Merck engaged in an extensive awareness and marketing campaign for HPV and Gardasil. Through these means, they sought to increase public knowledge of certain aspects of the disease and vaccine while submerging others. They carried out these actions due to the conclusion that by increasing the perceived need of the product while eliminating the cultural associations with sexuality, they could maximize profits. These efforts proved to be consequential, though, as Merck appeared as a coercive and capital-driven actor despite inventing a product that would be a public good.

Merck and the population stood to benefit immensely from Gardasil, Merck in terms of substantial profits and the public in terms of improved protection against a dangerous infection. The extent of these benefits, though, relied upon vast vaccine uptake amongst the population. Assuming a reliance upon the existing infrastructure for vaccines, Merck and many public health advocates sought to accomplish such a task through legislation for school-aged mandates. Citing the successes of a similar vaccine that they produced years earlier, Recombivax, Merck set out to lobby for the enactment of vaccine policy. However, these lobbying efforts proved to be disastrous when they were revealed to the public. The marketing and lobbying efforts Merck

engaged in for Gardasil resulted in increased scrutiny amongst policymakers and the public. Policies focused on implementing HPV vaccine mandates ultimately proved to be unsuccessful with sparing exceptions. The varieties of skepticism that were directed at the vaccine and its associated policies highlighted the cultural divide that existed within America.

HPV vaccines have failed to be effectively utilized by the American public in the wake of the complicated events of the late 2000's. Institutional barriers to HPV vaccination have been reduced and many vaccination initiatives have been conducted as an effort to overcome this nationwide reluctance. Of the initiatives implemented, environmental interventions produced the largest increase in vaccination and had the greatest reach. However, their success in America is limited by a vaccine infrastructure that relies on institutional mandates and clinical administration. Acknowledging this American deficiency, an approach that utilizes a combination of informational and multi-armed behavioral interventions represents the best method for national HPV vaccine improvement. To best implement this line of attack, efforts should be made to account for the diversity of the nation. Since the American people are not a generalizable group, public health efforts must incorporate the variation in sociodemographic characteristics into their initiative calculus. By utilizing a local approach that integrates community dynamics, HPV vaccination initiatives can be optimized.

The HPV vaccine has told a compelling story in America. It captivates the complex experiences of a population that struggles to manage the influences of corporations and government; the cultural divisions of gender and sexuality; the disparities in access to affordable healthcare; and the appropriate balance between individual liberty and governmental authority. These complexities have persisted through the years and in some cases have deepened. History

doesn't repeat itself but it does rhyme, and the eventual coronavirus vaccine will ignite these sensitivities once more. The HPV vaccine tells a compelling story in America, but will we listen?

## References

- AAP. (n.d.). *Grand Rounds / Resident Teaching Sessions*. AAP.Org. Retrieved May 9, 2020, from <http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/HPV-Champion-Toolkit/Pages/Grand-Rounds.aspx>
- Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children—United States, 1990-1998*. (n.d.). Retrieved November 14, 2019, from <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm>
- Alba, A., Cararach, M., & Rodríguez-Cerdeira, C. (2009). *The Human Papillomavirus (HPV) in Human Pathology: Description, Pathogenesis, Oncogenic Role, Epidemiology and Detection Techniques*. <https://doi.org/10.2174/1874372200903010090>
- Albeck-Ripka, L. (2018, October 3). In Australia, Cervical Cancer Could Soon Be Eliminated. *The New York Times*. <https://www.nytimes.com/2018/10/03/world/australia/cervical-cancer-hpv-vaccine.html>
- Allison, M. A., Hurley, L. P., Markowitz, L., Crane, L. A., Brtnikova, M., Beaty, B. L., Snow, M., Cory, J., Stokley, S., Roark, J., & Kempe, A. (2016). Primary Care Physicians' Perspectives About HPV Vaccine. *Pediatrics*. <https://doi.org/10.1542/peds.2015-2488>
- Aronowitz, R. (2010). Gardasil: A Vaccine against Cancer and a Drug to Reduce Risk. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 21–38). Johns Hopkins University Press.
- Ault, K. A. (2006). Epidemiology and Natural History of Human Papillomavirus Infections in the Female Genital Tract. *Infectious Diseases in Obstetrics and Gynecology, 2006*. <https://doi.org/10.1155/IDOG/2006/40470>

- Bäfverstedt, B. (1967). Condylomata acuminata—Past and present. *Acta Dermato-Venereologica*, 47(5), 376–381.
- Bailey, R. (2007, March 20). Why Aren't More Girls Getting the HPV Vaccine? *Detroit Free Press*.
- Barraza, L., Weidenaar, K., Campos-Outcalt, D., & Yang, Y. T. (2016). Human Papillomavirus and Mandatory Immunization Laws. *Public Health Reports*, 131(5), 728–731. <https://doi.org/10.1177/0033354916663184>
- Beavis, A., Krakow, M., Levinson, K., & Rositch, A. F. (2018). Reasons for Lack of HPV Vaccine Initiation in NIS-Teen Over Time: Shifting the Focus from Gender and Sexuality to Necessity and Safety. *Journal of Adolescent Health*, 63(5), 652–656. <https://doi.org/10.1016/j.jadohealth.2018.06.024>
- Blake, K. D., Ottenbacher, A. J., Rutten, L. J. F., Grady, M. A., Kobrin, S. C., Jacobson, R. M., & Hesse, B. W. (2015). Predictors of Human Papillomavirus Awareness and Knowledge in 2013. *American Journal of Preventive Medicine*, 48(4), 402–410. <https://doi.org/10.1016/j.amepre.2014.10.024>
- Bogel-Burroughs, N. (2020, May 2). Anti-Vaccination Activists Are Growing Force at Virus Protests. *The New York Times*. <https://www.nytimes.com/2020/05/02/us/anti-vaxxers-coronavirus-protests.html>
- Brandeis, L. D. & Supreme Court of The United States. (1922) U.S. Reports: *Zucht v. King*, 260 U.S. 174. [Periodical] Re.
- Braun, L., & Phoun, L. (2010). HPV Vaccination Campaigns: Masking Uncertainty, Erasing Complexity. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 39–60). The Johns Hopkins University Press.

- Brisson, M., Van De Velde, N., & Boily, M. (2009). Economic Evaluation of Human Papillomavirus Vaccination in Developed Countries. *Public Health Genomics; Basel*, 12(5–6), 343–351. <http://dx.doi.org/10.1159/000214924>
- Brotherton, J. M. L., Deeks, S. L., Campbell-Lloyd, S., Misrachi, A., Passaris, I., Peterson, K., Pitcher, H., Scully, M., Watson, M., & Webby, R. (2008). Interim estimates of human papillomavirus vaccination coverage in the school-based program in Australia. *Communicable Diseases Intelligence Quarterly Report*, 32(4), 457–461.
- Brotherton, J. M. L., Murray, S. L., Hall, M. A., Andrewartha, L. K., Banks, C. A., Meijer, D., Pitcher, H. C., Scully, M. M., & Molchanoff, L. (2013). Human papillomavirus vaccine coverage among female Australian adolescents: Success of the school-based approach. *The Medical Journal of Australia*, 199(9), 614–617.  
<https://doi.org/10.5694/mja13.10272>
- Brotherton, J. M. L., Zuber, P. L. F., & Bloem, P. J. N. (2016). Primary Prevention of HPV through Vaccination: Update on the Current Global Status. *Current Obstetrics and Gynecology Reports*, 5(3), 210–224. <https://doi.org/10.1007/s13669-016-0165-z>
- Browse the SEER Cancer Statistics Review 1975-2017*. (n.d.). SEER. Retrieved May 8, 2020, from  
[https://seer.cancer.gov/csr/1975\\_2017/browse\\_csr.php?sectionSEL=1&pageSEL=sect\\_01\\_table.28](https://seer.cancer.gov/csr/1975_2017/browse_csr.php?sectionSEL=1&pageSEL=sect_01_table.28)
- Bruni, L., Diaz, M., Barrionuevo-Rosas, L., Herrero, R., Bray, F., Bosch, F. X., de Sanjosé, S., & Castellsagué, X. (2016). Global estimates of human papillomavirus vaccination coverage by region and income level: A pooled analysis. *The Lancet Global Health*, 4(7), e453–e463. [https://doi.org/10.1016/S2214-109X\(16\)30099-7](https://doi.org/10.1016/S2214-109X(16)30099-7)

Buchwald, E. (n.d.). *There's no guarantee that a coronavirus vaccine will be affordable.*

MarketWatch. Retrieved May 9, 2020, from <https://www.marketwatch.com/story/this-is-what-has-to-happen-for-a-coronavirus-vaccine-to-be-affordable-2020-02-29>

Bui, Q., & Miller, C. C. (2018, August 4). The Age That Women Have Babies: How a Gap Divides America. *The New York Times*.

<https://www.nytimes.com/interactive/2018/08/04/upshot/up-birth-age-gap.html>,

<https://www.nytimes.com/interactive/2018/08/04/upshot/up-birth-age-gap.html>

Burd, E. M. (2003). Human Papillomavirus and Cervical Cancer. *Clinical Microbiology Reviews*, 16(1), 1–17. <https://doi.org/10.1128/CMR.16.1.1-17.2003>

Bustillos, D. (2016). Political Pitfalls in Policymaking: The Texas HPV Vaccine Policy

Saga. *Narrative Inquiry in Bioethics*, 6(1), 6–10. <https://doi.org/10.1353/nib.2016.0040>

Caffrey, M. (2018, March 25). *Boys Don't Get HPV Vaccination Because Doctors Don't*

*Recommend It, Study Finds*. AJMC. <https://www.ajmc.com/conferences/sgo-2018/boys-dont-get-hpv-vaccination-because-doctors-dont-recommend-it-study-finds>

Cancer Vaccine Bills Stall: Sex, Parenting, Politics: "Perfect Storm" of Controversy Slows Acceptance". (2007, May 27). *Grand Rapids Press*.

Caskey, R., Andes, S., & Walton, S. M. (2016). HPV vaccine: Less is more. *Vaccine*,

34(16), 1863–1864. <https://doi.org/10.1016/j.vaccine.2016.02.022>

Caskey, R. N., Macario, E., Johnson, D. C., Hamlish, T., & Alexander, K. A. (2013). A

School-Located Vaccination Adolescent Pilot Initiative in Chicago: Lessons Learned.

*Journal of the Pediatric Infectious Diseases Society*, 2(3), 198–204.

<https://doi.org/10.1093/jpids/pit001>

- Casper, M. J., & Carpenter, L. M. (2008). Sex, drugs, and politics: The HPV vaccine for cervical cancer. *Sociology of Health & Illness*, 30(6), 886–899.  
<https://doi.org/10.1111/j.1467-9566.2008.01100.x>
- Cassidy, B., Braxter, B., Charron-Prochownik, D., & Schlenk, E. A. (2014). A quality improvement initiative to increase HPV vaccine rates using an educational and reminder strategy with parents of preteen girls. *Journal of Pediatric Health Care: Official Publication of National Association of Pediatric Nurse Associates & Practitioners*, 28(2), 155–164. <https://doi.org/10.1016/j.pedhc.2013.01.002>
- Cates, J. R., Diehl, S. J., Crandell, J. L., & Coyne-Beasley, T. (2014). Intervention effects from a social marketing campaign to promote HPV vaccination in preteen boys. *Vaccine*, 32(33), 4171–4178. <https://doi.org/10.1016/j.vaccine.2014.05.044>
- CDC. (2012, April 20). *Human Papillomavirus—Associated Cancers—United States, 2004–2008*. Morbidity and Mortality Weekly Report.  
[https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6115a2.htm?s\\_cid=mm6115a2\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6115a2.htm?s_cid=mm6115a2_w)
- CDC. (2019, March 4). *NVSS - Mortality Tables—General Mortality—GMWKI*.  
<https://www.cdc.gov/nchs/nvss/mortality/gmwki.htm>
- CDC. (2020, March 27). *How Many Cancers Are Linked with HPV Each Year?* | CDC.  
<https://www.cdc.gov/cancer/hpv/statistics/cases.htm>
- Centers for Disease Control and Prevention (U.S.) (Ed.). (1986). *MMWR. Morbidity and mortality weekly report, Vol. 35, no. 2, January 17, 1986* (cdc:35444). 35(2).  
<https://stacks.cdc.gov/view/cdc/35444>
- Cervical Cancer Causes, Diagnosis and Symptoms: NCCC*. (n.d.). Retrieved May 15, 2019, from <https://www.nccc-online.org/hpvcervical-cancer/cervical-cancer-overview/>

*Cervical Cancer Statistics* | CDC. (2019a, July 29).

<https://www.cdc.gov/cancer/cervical/statistics/index.htm>

*Cervical Cancer Statistics* | CDC. (2019b, July 29).

<https://www.cdc.gov/cancer/cervical/statistics/index.htm>

Chao, C., Preciado, M., Slezak, J., & Xu, L. (2015). A randomized intervention of reminder letter for human papillomavirus vaccine series completion. *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine*, 56(1), 85–90.

<https://doi.org/10.1016/j.jadohealth.2014.08.014>

*Chapter One (Background)*. (n.d.). Google Docs. Retrieved May 8, 2020, from

[https://docs.google.com/document/d/1bP2ZrKNAOdFLHm96S8iLNcLNlx0PrOeZ80GP9qRnFBQ/edit?usp=embed\\_facebook](https://docs.google.com/document/d/1bP2ZrKNAOdFLHm96S8iLNcLNlx0PrOeZ80GP9qRnFBQ/edit?usp=embed_facebook)

Charles, A. S. (2007). *The Texas Controversy Over the Cervical Cancer Vaccine* (SSRN Scholarly Paper ID 1691696). Social Science Research Network.

<https://papers.ssrn.com/abstract=1691696>

Charo, R. A. (2007). Politics, parents, and prophylaxis—Mandating HPV vaccination in the United States. *The New England Journal of Medicine*, 356(19), 1905–1908.

<https://doi.org/10.1056/NEJMp078054>

Chaturvedi, A. K., Engels, E. A., Pfeiffer, R. M., Hernandez, B. Y., Xiao, W., Kim, E., Jiang, B., Goodman, M. T., Sibug-Saber, M., Cozen, W., Liu, L., Lynch, C. F., Wentzensen, N., Jordan, R. C., Altekruze, S., Anderson, W. F., Rosenberg, P. S., & Gillison, M. L. (2011). Human papillomavirus and rising oropharyngeal cancer incidence in the United States. *Journal of Clinical Oncology: Official Journal of the*

*American Society of Clinical Oncology*, 29(32), 4294–4301. PubMed.

<https://doi.org/10.1200/JCO.2011.36.4596>

Chesler, G., & Kessler, B. (2010). Re-Presenting Choice: Tune in HPV. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 146–162). The Johns Hopkins University Press.

Childs, D. (2007, February 27). *Political Intrigue in Merck's HPV Vaccine Push*. ABC News. <https://abcnews.go.com/Health/story?id=2890402&page=1>

Clifford, G. M., Smith, J. S., Plummer, M., Muñoz, N., & Franceschi, S. (2003). Human papillomavirus types in invasive cervical cancer worldwide: A meta-analysis. *British Journal of Cancer*, 88(1), 63–73. <https://doi.org/10.1038/sj.bjc.6600688>

Colgrove, J. (2006). The Ethics and Politics of Compulsory HPV Vaccination. *The New England Journal of Medicine; Boston*, 355(23), 2389–2391.

Colgrove, J. (2010). The Coercive Hand, the Beneficent Hand: What the History of Compulsory Vaccination Can Tell Us about HPV Vaccine Mandates. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 3–21). The Johns Hopkins University Press.

Colgrove, J., Mello, M. M., & Abiola, S. E. (2013). The Politics of HPV Vaccination Policy Formation in the United States. *Journal of Health Politics, Policy and Law*, 38(4), 645–681. <https://doi.org/10.1215/03616878-2208567>

Conrey, R., Valencia, V., Cioletti, A., & Williams-Brown, M. (2020). Regional variation in human papillomavirus vaccination uptake and completion among adolescents 13–17 in the state of Texas. *Vaccine*. <https://doi.org/10.1016/j.vaccine.2020.03.059>

- Coughlin, S. S., Richards, T. B., Nasser, K., Weiss, N. S., Wiggins, C. L., Saraiya, M., Stinchcomb, D. G., Venson, V. M., & Nielson, C. M. (2008). Cervical cancer incidence in the United States in the US-Mexico border region, 1998-2003. *Cancer*, *113*(10 Suppl), 2964–2973. <https://doi.org/10.1002/cncr.23748>
- cultural cognition project - Cultural Cognition Blog - A case study: The HPV vaccine disaster (Science of Science Communication Course, Session 1)*. (n.d.). Retrieved November 25, 2019, from <http://www.culturalcognition.net/blog/2013/1/21/a-case-study-the-hpv-vaccine-disaster-science-of-science-com.html>
- Daley, E. M., Vamos, C. A., Thompson, E. L., Zimet, G. D., Rosberger, Z., Merrell, L., & Kline, N. S. (2017). The feminization of HPV: How science, politics, economics and gender norms shaped U.S. HPV vaccine implementation. *Papillomavirus Research*, *3*, 142–148. <https://doi.org/10.1016/j.pvr.2017.04.004>
- Daley, M. F., Kempe, A., Pyrzanowski, J., Vogt, T. M., Dickinson, L. M., Kile, D., Fang, H., Rinehart, D. J., & Shlay, J. C. (2014). School-located vaccination of adolescents with insurance billing: Cost, reimbursement, and vaccination outcomes. *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine*, *54*(3), 282–288. <https://doi.org/10.1016/j.jadohealth.2013.12.011>
- Davidson, T. (2017). *Vaccines: History, Science, and Issues*. ABC-CLIO, LLC. <http://ebookcentral.proquest.com/lib/utxa/detail.action?docID=4865674>
- Davis, E. (2017). What is It to Share Contraceptive Responsibility? *Topoi*, *36*(3), 489–499. <https://doi.org/10.1007/s11245-015-9342-3>
- de Martel, C., Ferlay, J., Franceschi, S., Vignat, J., Bray, F., Forman, D., & Plummer, M. (2012). Global burden of cancers attributable to infections in 2008: A review and

synthetic analysis. *The Lancet. Oncology*, 13(6), 607–615.

[https://doi.org/10.1016/S1470-2045\(12\)70137-7](https://doi.org/10.1016/S1470-2045(12)70137-7)

de Melo-Martín, I. (2006). The promise of the human papillomavirus vaccine does not confer immunity against ethical reflection. *The Oncologist*, 11(4), 393–396.

<https://doi.org/10.1634/theoncologist.11-4-393>

Dempsey, A. F., & Patel, D. A. (2010). HPV vaccine acceptance, utilization and expected impacts in the U.S. *Human Vaccines*, 6(9), 715–720.

<https://doi.org/10.4161/hv.6.9.12730>

Department of Health and Human Services, & Centers for Disease Control and Prevention. (2019, October 22). *Vaccine Information Statement | Hepatitis B | VIS | CDC*.

<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.html>

Dickerson, J. B., Smith, M. L., & Ory, M. G. (2011). Increasing uptake of Gardasil among American adolescents: Comparisons with the history of Hepatitis B vaccination. *Human Vaccines*, 7(2), 211–219. <https://doi.org/10.4161/hv.7.2.13633>

Dietz, B. (2006, May 23). Vaccine Prevents Cervical Cancer: So, What's the Down Side? *The New York Times*.

Dietz, C. A., & Nyberg, C. R. (2011). Genital, Oral, and Anal Human Papillomavirus Infection in Men Who Have Sex With Men. *The Journal of the American Osteopathic Association*, 111(3\_suppl\_2), S19–S25.

Douglas, A. (1998). *Feminization of American Culture*. Farrar, Straus and Giroux.

Down There Health Collective. (2007). *HPV Zine*. <https://myspace.com/downtherehealth>

Drutman, L. (2015, April 20). *How Corporate Lobbyists Conquered American Democracy*.

The Atlantic. <https://www.theatlantic.com/business/archive/2015/04/how-corporate-lobbyists-conquered-american-democracy/390822/>

Duffy, J. (1978). School Vaccination: The Precursor to School Medical Inspection. *Journal of the History of Medicine and Allied Sciences*, XXXIII(3), 344–355.

<https://doi.org/10.1093/jhmas/XXXIII.3.344>

Elliott, J., & Ackerman, T. (2007, February 3). Perry vaccine move stirs money, sexual concerns. *Houston Chronicle*. [https://www.chron.com/news/health/article/Perry-](https://www.chron.com/news/health/article/Perry-vaccine-move-stirs-money-sexual-concerns-1801490.php)

[vaccine-move-stirs-money-sexual-concerns-1801490.php](https://www.chron.com/news/health/article/Perry-vaccine-move-stirs-money-sexual-concerns-1801490.php)

English, A., Shaw, F. E., McCauley, M. M., & Fishbein, D. B. (2008). Legal Basis of Consent for Health Care and Vaccination for Adolescents. *Pediatrics*, 121(Supplement 1), S85–S87. <https://doi.org/10.1542/peds.2007-1115J>

Epstein, S. (2010). The Great Undiscussable: Anal Cancer, HPV, and Gay Men’s Health. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine’s Simple Solutions* (pp. 61–90). The Johns Hopkins University Press.

Fairley, C. K., & Donovan, B. (2010). What can surveillance of genital warts tell us? *Sexual Health*, 7(3), 325–327. <https://doi.org/10.1071/SH09145>

*Fast Facts | HPV*. (n.d.). American Sexual Health Association. Retrieved May 9, 2020, from <http://www.ashasexualhealth.org/stdsstis/hpv/fast-facts/>

Fay, L. (2019, August). *Do You Know How Much the Gardasil Vaccine Costs?* Verywell Health. <https://www.verywellhealth.com/how-much-does-the-gardasil-vaccine-cost-582021>

- Fiks, A. G., Grundmeier, R. W., Mayne, S., Song, L., Feemster, K., Karavite, D., Hughes, C. C., Massey, J., Keren, R., Bell, L. M., Wasserman, R., & Localio, A. R. (2013). Effectiveness of decision support for families, clinicians, or both on HPV vaccine receipt. *Pediatrics*, *131*(6), 1114–1124. <https://doi.org/10.1542/peds.2012-3122>
- Foundation, K. F. (2000). *National Survey of Public Knowledge of HPV, the Human Papillomavirus*.
- Franco, M., Mazzucca, S., Padek, M., & Brownson, R. C. (2019). Going beyond the individual: How state-level characteristics relate to HPV vaccine rates in the United States. *BMC Public Health*, *19*(1), 246. <https://doi.org/10.1186/s12889-019-6566-y>
- Freeman HP, & Wingrove BK. (2005). Excess Cervical Cancer Mortality: A Marker for Low Access to Health Care in Poor Communities. *National Cancer Institute, Center to Reduce Cancer Health Disparities*, 96.
- Fu, L. Y., Bonhomme, L.-A., Cooper, S. C., Joseph, J. G., & Zimet, G. D. (2014). Educational interventions to increase HPV vaccination acceptance: A systematic review. *Vaccine*, *32*(17), 1901–1920. <https://doi.org/10.1016/j.vaccine.2014.01.091>
- Garber, J. (2017, November 14). *HPV protection or cancer vaccine? Putting Gardasil in context*. Lown Institute. <https://lowninstitute.org/news/hpv-vaccine-cancer-vaccine-putting-gardasil-context/>
- Garnock-Jones, K. P., & Giuliano, A. R. (2011). Quadrivalent human papillomavirus (HPV) types 6, 11, 16, 18 vaccine: For the prevention of genital warts in males. *Drugs*, *71*(5), 591–602. <https://doi.org/10.2165/11205980-000000000-00000>
- Gerend, M. A., & Shepherd, J. E. (2012). Predicting human papillomavirus vaccine uptake in young adult women: Comparing the health belief model and theory of planned

- behavior. *Annals of Behavioral Medicine: A Publication of the Society of Behavioral Medicine*, 44(2), 171–180. <https://doi.org/10.1007/s12160-012-9366-5>
- Gibbs, N. (2006, June 21). Defusing the War Over the “Promiscuity” Vaccine. *Time*.  
<http://content.time.com/time/nation/article/0,8599,1206813,00.html>
- Gilkey, M. B., Dayton, A. M., Moss, J. L., Sparks, A. C., Grimshaw, A. H., Bowling, J. M., & Brewer, N. T. (2014). Increasing provision of adolescent vaccines in primary care: A randomized controlled trial. *Pediatrics*, 134(2), e346-353.  
<https://doi.org/10.1542/peds.2013-4257>
- Gilkey, M. B., Malo, T. L., & Brewer, N. T. (2016). Quality of Physician Communication about HPV Vaccine – Reply. *Cancer Epidemiology, Biomarkers & Prevention : A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology*, 25(5), 868. <https://doi.org/10.1158/1055-9965.EPI-16-0113>
- Godlee, F., Smith, J., & Marcovitch, H. (2011). Wakefield’s article linking MMR vaccine and autism was fraudulent. *BMJ*. <https://doi.org/10.1136/bmj.c7452>
- Gold, R., Naleway, A. L., Jenkins, L. L., Riedlinger, K. K., Kurosky, S. K., Nystrom, R. J., & Kurilo, M. B. (2011). Completion and timing of the three-dose human papillomavirus vaccine series among adolescents attending school-based health centers in Oregon. *Preventive Medicine*, 52(6), 456–458. <https://doi.org/10.1016/j.ypmed.2011.04.010>
- Gottlieb, S. (2018). *Not Quite a Cancer Vaccine: Selling HPV and Cervical Cancer*. Rutgers University Press.
- Grady, D. (2007, March 6). A Vital Discussion, Clouded. *The New York Times*.  
<https://www.nytimes.com/2007/03/06/health/06seco.html>

- Harper, D. M., & DeMars, L. R. (2017). HPV vaccines – A review of the first decade. *Gynecologic Oncology*, 146(1), 196–204. <https://doi.org/10.1016/j.ygyno.2017.04.004>
- Healthcare-Professional-Key-Messages-508.pdf*. (n.d.). Retrieved May 7, 2020, from <https://www.cdc.gov/vaccines/events/niam/downloads/Healthcare-Professional-Key-Messages-508.pdf>
- Hepatitis B Foundation. (2020). *What is Hepatitis B?* <https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/>
- Hill, H. A. (2018). Vaccination Coverage Among Children Aged 19–35 Months—United States, 2017. *MMWR. Morbidity and Mortality Weekly Report*, 67. <https://doi.org/10.15585/mmwr.mm6740a4>
- HINTS\_Brief\_26.pdf*. (n.d.). Retrieved April 29, 2020, from [https://hints.cancer.gov/docs/Briefs/HINTS\\_Brief\\_26.pdf](https://hints.cancer.gov/docs/Briefs/HINTS_Brief_26.pdf)
- Hoffman, J. (2019, September 23). How Anti-Vaccine Sentiment Took Hold in the United States. *The New York Times*. <https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html>
- Hopfer, S. (2012). Effects of a narrative HPV vaccination intervention aimed at reaching college women: A randomized controlled trial. *Prevention Science: The Official Journal of the Society for Prevention Research*, 13(2), 173–182. <https://doi.org/10.1007/s11121-011-0254-1>
- HPV infection—Symptoms and causes*. (n.d.). Mayo Clinic. Retrieved May 8, 2020, from <https://www.mayoclinic.org/diseases-conditions/hpv-infection/symptoms-causes/syc-20351596>

*Human Papillomavirus (HPV) Vaccines to Prevent Cancer* • *iBiology*. (n.d.). IBiology.

Retrieved May 8, 2020, from <https://www.ibiology.org/human-disease/hpv/>

Hussain, A., Ali, S., Ahmed, M., & Hussain, S. (2018). The Anti-vaccination Movement: A

Regression in Modern Medicine. *Cureus*, *10*(7). <https://doi.org/10.7759/cureus.2919>

Jenco, M. (2019). Study: Physicians make stronger HPV vaccination recommendations for older children. *Infectious Diseases*, *2*.

Johnson. (1964, September 7). *Political Ad: "Daisy Ad."*

<https://archives.nbclearn.com/portal/site/k-12/browse/?cuecard=2362>

Kempe, A., Barrow, J., Stokley, S., Saville, A., Glazner, J. E., Suh, C., Federico, S.,

Abrams, L., Seewald, L., Beaty, B., Daley, M. F., & Dickinson, L. M. (2012).

Effectiveness and cost of immunization recall at school-based health centers.

*Pediatrics*, *129*(6), e1446-1452. <https://doi.org/10.1542/peds.2011-2921>

Kempe, A., O'Leary, S. T., Markowitz, L. E., Crane, L. A., Hurley, L. P., Brtnikova, M.,

Beaty, B. L., Meites, E., Stokley, S., & Lindley, M. C. (2019). HPV Vaccine Delivery Practices by Primary Care Physicians. *Pediatrics*, *144*(4).

<https://doi.org/10.1542/peds.2019-1475>

Kharbanda, E. O., Stockwell, M. S., Fox, H. W., Andres, R., Lara, M., & Rickert, V. I.

(2011). Text message reminders to promote human papillomavirus vaccination.

*Vaccine*, *29*(14), 2537–2541. <https://doi.org/10.1016/j.vaccine.2011.01.065>

Kim, J. J. (2010). Targeted human papillomavirus vaccination of men who have sex with men in the USA: A cost-effectiveness modelling analysis. *The Lancet. Infectious*

*Diseases*, *10*(12), 845–852. [https://doi.org/10.1016/S1473-3099\(10\)70219-X](https://doi.org/10.1016/S1473-3099(10)70219-X)

King, M. (2004, September 10). *Toomey's out, Delisi's in*.

<https://www.austinchronicle.com/news/2004-09-10/228246/>

Korioth, T. (2018). Boost HPV vaccination rates with these 3 tools. *AAP News*.

<https://www.aappublications.org/news/2018/06/06/fyihpv060618>

Kreuter, M. W., & Wray, R. J. (2003). Tailored and Targeted Health Communication:

Strategies for Enhancing Information Relevance. *American Journal of Health Behavior*, 27(1), S227–S232.

KXAN.com. (2007, February 20). *Public Hearing on HPV Vaccine Went until Midnight*.

[https://www.kxan.com/Global/story.asp?S=6107668&nav=menu73\\_2\\_6](https://www.kxan.com/Global/story.asp?S=6107668&nav=menu73_2_6)

Lakoff, A. (2015). Vaccine Politics and the Management of Public Reason. *Public Culture*,

27(3 (77)), 419–425. <https://doi.org/10.1215/08992363-2896159>

Lam, B. (2015, February 10). *Vaccines Are Profitable, So What?* The Atlantic.

<https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/>

Lawmakers Rethinking How to Cure Cancer. (2007, June 9). *Grand Rapid Press*.

Lee, L., & Garland, S. M. (2017). Human papillomavirus vaccination: The population

impact. *FL000Research*, 6. <https://doi.org/10.12688/fl000research.10691.1>

Lehtinen, M., Pavane, J., Wheeler, C. M., Jaskaran, U., Garland, S. M., Castellsagué, X.,

Skinner, S. R., Pater, D., Nafud, P., Salmeron, J., Chow, S.-N., Kitchener, H., Teixeira,

J. C., Hedrick, J., Limon, G., Swarovski, A., Romanowski, B., Aoki, F. Y., Schwarz, T.

F., ... Dubbin, G. (2012). Overall efficacy of HPV-16/18 AS04-adjuvanted vaccine

against grade 3 or greater cervical intraepithelial neoplasia: 4-year end-of-study analysis

of the randomized, double-blind PATRICIA trial. *The Lancet Oncology*, 13(1), 89–99.

[https://doi.org/10.1016/S1470-2045\(11\)70286-8](https://doi.org/10.1016/S1470-2045(11)70286-8)

Levine, S. (2007, March 2). Parents Question HPV Vaccine, Push to Mandate Shots Rapidly Creates Backlash. *The Washington Post*.

Livingston, J., Walloon, K., & Cooper, B. (2010). Vaccination as Governance: HPV Skepticism in the United States and Africa, and the North-South Divide. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 231–253). The Johns Hopkins University Press.

Lo, B. (2006). HPV vaccine and adolescents' sexual activity. *BMJ: British Medical Journal*, 332(7550), 1106–1107.

Lowy, D. R., & Schiller, J. T. (2006). Prophylactic human papillomavirus vaccines. *The Journal of Clinical Investigation*, 116(5), 1167–1173. <https://doi.org/10.1172/JCI28607>

Macartney, K. K., Chiu, C., Georgousakis, M., & Brotherton, J. M. L. (2013). Safety of human papillomavirus vaccines: A review. *Drug Safety*, 36(6), 393–412.

<https://doi.org/10.1007/s40264-013-0039-5>

Mamo, L., & Epstein, S. (2017). The new sexual politics of cancer: Oncoviruses, disease prevention, and sexual health promotion. *BioSocieties; London*, 12(3), 367–391.

<http://dx.doi.org.ezproxy.lib.utexas.edu/10.1057/biosoc.2016.10>

Manhart, L. E., & Koutsky, L. A. (2002). Do Condoms Prevent Genital HPV Infection, External Genital Warts, or Cervical Neoplasia?: A Meta-Analysis. *Sexually Transmitted Diseases*, 29(11), 725.

- McGraw, S. L., & Ferrante, J. M. (2014). Update on prevention and screening of cervical cancer. *World Journal of Clinical Oncology*, 5(4), 744–752.  
<https://doi.org/10.5306/wjco.v5.i4.744>
- McQuillan, G., & Unger, E. R. (2017). *Prevalence of HPV in Adults Aged 18–69: United States, 2011–2014*. 280, 8.
- Measles explained: What’s behind the recent outbreaks?* (n.d.). Retrieved May 8, 2020, from <https://www.unicef.org/stories/measles-explained-whats-behind-recent-outbreaks>
- Mello, M. M., Abiola, S., & Colgrove, J. (2012). Pharmaceutical Companies’ Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination. *American Journal of Public Health; Washington*, 102(5), 893–898.
- Merck. (2005). *DDB - HPV.com—Tell Someone*.  
<https://www.youtube.com/watch?v=4yV7SpHOcrw>
- Merck. (2006). *One Less Commercial for Gardasil*.  
<https://www.youtube.com/watch?v=hJ8x3KR75fA>
- Mesher, D., Panwar, K., Thomas, S. L., Beddows, S., & Soldan, K. (2016). Continuing reductions in HPV 16/18 in a population with high coverage of bivalent HPV vaccination in England: An ongoing cross-sectional study. *BMJ Open*, 6(2), e009915.  
<https://doi.org/10.1136/bmjopen-2015-009915>
- Millikan, A. (2006, October 30). HPV vaccine goes unused. *The Michigan Daily*.  
<https://www.michigandaily.com/content/hpv-vaccine-goes-unused>
- Milloy, C. (2007, January 10). District’s HPV Proposal Tinged with Ugly Assumptions. *The Washington Post*.

- Molokwu, J., Dwivedi, A., Mallawaarachchi, I., Hernandez, A., & Shokar, N. (2019). Tiempo de Vacunarte (time to get vaccinated): Outcomes of an intervention to improve HPV vaccination rates in a predominantly Hispanic community. *Preventive Medicine, 121*, 115–120. <https://doi.org/10.1016/j.ypmed.2019.02.004>
- Moore, G. R., Crosby, R. A., Young, A., & Charnigo, R. (2010). Low rates of free human papillomavirus vaccine uptake among young women. *Sexual Health, 7*(3), 287–290. PubMed. <https://doi.org/10.1071/sh09136>
- More Re: Merck’s “Help Pay for Vioxx” Mandatory Vaccine Campaign. (2007, February 8). *Alliance for Human Research Protection*. <https://ahrp.org/more-re-mercks-help-pay-for-vioxx-mandatory-vaccine-campaign/>
- Most American adults do not know that HPV causes oral, anal, and penile cancers.* (n.d.). EurekAlert! Retrieved April 29, 2020, from [https://www.eurekalert.org/pub\\_releases/2019-09/uoth-maa091219.php](https://www.eurekalert.org/pub_releases/2019-09/uoth-maa091219.php)
- National Conference of State Legislatures. (2018, June 12). *HPV Vaccine: State Legislation and Statutes*. <https://www.ncsl.org/research/health/hpv-vaccine-state-legislation-and-statutes.aspx>
- Navarrete, J. P., Padilla, M. E., Castro, L. P., & Rivera, J. O. (2014). Development of a community pharmacy human papillomavirus vaccine program for underinsured university students along the United States/Mexico border. *Journal of the American Pharmacists Association: JAPhA, 54*(6), 642–647. <https://doi.org/10.1331/JAPhA.2014.13222>

NCI Dictionary of Cancer Terms (nciglobal,ncicenterprise). (2011, February 2).

[NciAppModulePage]. National Cancer Institute.

<https://www.cancer.gov/publications/dictionaries/cancer-terms>

NHPC Press Release: Schools Teaching Prevention | 2015 | Newsroom | NCHHSTP | CDC.

(2019, May 21). <https://www.cdc.gov/nchhstp/newsroom/2015/nhpc-press-release-schools-teaching-prevention.html>

NIH. (1996). *The National Institutes of Health (NIH) Consensus Development Program:*

*Cervical Cancer.* <https://consensus.nih.gov/1996/1996cervicalcancer102html.htm>

NormileMay. 11, D., 2018, & Pm, 12:25. (2018, May 11). *Journal retracts paper claiming*

*neurological damage from HPV vaccine.* Science | AAAS. <https://www.sciencemag.org.ezproxy.lib.utexas.edu/news/2018/05/journal-retracts-paper-claiming-neurological-damage-hpv-vaccine>

Office of Disease Prevention and Health Promotion. (2010). *Immunization and Infectious*

*Diseases | Healthy People 2020.* <https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>

Opel, D. J., Mangione-Smith, R., Robinson, J. D., Heritage, J., De Vere, V., Salas, H. S.,

Zhou, C., & Taylor, J. A. (2015). The Influence of Provider Communication Behaviors on Parental Vaccine Acceptance and Visit Experience. *American Journal of Public Health, 105*(10), 1998–2004. <https://doi.org/10.2105/AJPH.2014.302425>

Osazuwa-Peters, N., Adjei Boakye, E., Mohammed, K. A., Tobo, B. B., Geneus, C. J., &

Schootman, M. (2017). Not just a woman's business! Understanding men and women's knowledge of HPV, the HPV vaccine, and HPV-associated cancers. *Preventive Medicine, 99*, 299–304. <https://doi.org/10.1016/j.ypmed.2017.03.014>

Oudshoorn, N. (Ed.). (2003). Designing Technology and Masculinity: Challenging the Invisibility of Male Reproductive Bodies in Scientific Medicine. In *The Male Pill: A Biography of a Technology in the Making* (p. 0). Duke University Press.

<https://doi.org/10.1215/9780822385226-001>

*Pap Smear | Additional Resources | Imaginis—The Women's Health & Wellness Resource Network.* (n.d.). Retrieved May 8, 2020, from <https://www.imaginis.com/womens-health/pap-smear-2>

*Pelling: Contagion: Historical and Cultural Studies—Google Scholar.* (n.d.). Retrieved May 15, 2019, from [https://scholar.google.com/scholar\\_lookup?hl=en&publication\\_year=2001&author=A.+Bashford&author=C.+Hooker&title=Contagion%3A+Historical+and+Cultural+Studies](https://scholar.google.com/scholar_lookup?hl=en&publication_year=2001&author=A.+Bashford&author=C.+Hooker&title=Contagion%3A+Historical+and+Cultural+Studies)

Perkins, R. B., Zisblatt, L., Legler, A., Trucks, E., Hanchate, A., & Gorin, S. S. (2015). Effectiveness of a provider-focused intervention to improve HPV vaccination rates in boys and girls. *Vaccine*, 33(9), 1223–1229.

<https://doi.org/10.1016/j.vaccine.2014.11.021>

Perry, R. (2007). *Statement of Gov. Rick Perry on HPV Vaccine Executive Order.*

Polzer, J. C., & Knabe, S. M. (2012). From desire to disease: Human papillomavirus (HPV) and the medicalization of nascent female sexuality. *Journal of Sex Research*, 49(4), 344–352. <https://doi.org/10.1080/00224499.2011.644598>

Prescott, H. (2010). Safeguarding Girls: Morality, Risk, and Activism. In *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions* (pp. 103–120). The Johns Hopkins University Press.

Radosevich, J. (2012). *HPV and Cancer.* Springer.

- Rahman, M., McGrath, C. J., & Berenson, A. B. (2014). Geographic variation in human papillomavirus vaccination uptake among 13-17 year old adolescent girls in the United States. *Vaccine*, 32(21), 2394–2398. <https://doi.org/10.1016/j.vaccine.2014.02.097>
- Reagan-Steiner, S., Yankey, D., Jeyarajah, J., Elam-Evans, L. D., Singleton, J. A., Curtis, C. R., MacNeil, J., Markowitz, L. E., & Stokley, S. (2015). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years—United States, 2014. *MMWR. Morbidity and Mortality Weekly Report*, 64(29), 784–792. PubMed. <https://doi.org/10.15585/mmwr.mm6429a3>
- Redmond, M. A. (2011). *A Critical Discourse Analysis of the Marketing of Merck & Co.'s Human Papillomavirus Vaccine Gardasil®*. 94.
- Rickert, V. I., Auslander, B. A., Cox, D. S., Rosenthal, S. L., Rupp, R. E., & Zimet, G. D. (2015). School-based HPV immunization of young adolescents: Effects of two brief health interventions. *Human Vaccines & Immunotherapeutics*, 11(2), 315–321. <https://doi.org/10.1080/21645515.2014.1004022>
- Rothman, S. M., & Rothman, D. J. (2009). Marketing HPV vaccine: Implications for adolescent health and medical professionalism. *JAMA*, 302(7), 781–786. <https://doi.org/10.1001/jama.2009.1179>
- Russell, L. B., Gold, M. R., Siegel, J. E., Daniels, N., & Weinstein, M. C. (1996). The role of cost-effectiveness analysis in health and medicine. Panel on Cost-Effectiveness in Health and Medicine. *JAMA*, 276(14), 1172–1177.
- Safaeian, M., Sampson, J. N., Pan, Y., Porras, C., Kemp, T. J., Herrero, R., Quint, W., van Doorn, L. J., Schussler, J., Lowy, D. R., Schiller, J., Schiffman, M. T., Rodriguez, A. C., Gail, M. H., Hildesheim, A., Gonzalez, P., Pinto, L. A., Kreimer, A. R., & Costa

- Rica HPV Vaccine Trial (CVT) Group. (2018). Durability of Protection Afforded by Fewer Doses of the HPV16/18 Vaccine: The CVT Trial. *Journal of the National Cancer Institute*, 110(2). <https://doi.org/10.1093/jnci/djx158>
- Schiffman, M., Castle, P. E., Jeronimo, J., Rodriguez, A. C., & Wacholder, S. (2007). Human papillomavirus and cervical cancer. *Lancet*, 370, 18.
- Schuchat, A. (2015). HPV “Coverage.” *New England Journal of Medicine*, 372(8), 775–776. <https://doi.org/10.1056/NEJMe1415742>
- Siers-Poisson, J. (2007). *Research, Develop, and Sell, Sell, Sell: Part Two in a series on the Politics and PR of Cervical Cancer*. <http://www.prwatch.org/news/207/06/6208>
- Siers-Poisson, Judith. (2007, July 10). *Women in Government, Merck’s Trojan Horse: Part Three in a Series on the Politics and PR of Cervical Cancer | Center for Media and Democracy*. <https://web.archive.org/web/20081201131753/http://www.prwatch.org/node/6232/>
- Silverman, E. (2005, April 12). “Parents Balk at Idea of STD Vaccine for Kids.” *Muskegon (MI) Chronicle*.
- Spinner, C., Ding, L., Bernstein, D. I., Brown, D. R., Franco, E. L., Covert, C., & Kahn, J. A. (2019). Human Papillomavirus Vaccine Effectiveness and Herd Protection in Young Women. *Pediatrics*, 143(2). <https://doi.org/10.1542/peds.2018-1902>
- STD Facts—Human papillomavirus (HPV)*. (2019, September 12). <https://www.cdc.gov/std/hpv/stdfact-hpv.htm>
- Street, W. (1930). *Cancer Facts & Figures 2019*. 76.

- Stubbs, B. W., Panizza, C. A., Moss, J. L., Reiter, P. L., Whitesell, D. H., & Brewer, N. T. (2014). Evaluation of an intervention providing HPV vaccine in schools. *American Journal of Health Behavior*, 38(1), 92–102. <https://doi.org/10.5993/AJHB.38.1.10>
- Suk, R., Montrealer, J. R., Nimule, G. S., Nitra, A. G., Scheler, K. M., Sona wane, K., & Deshmukh, A. A. (2019). Public Knowledge of Human Papillomavirus and Receipt of Vaccination Recommendations. *JAMA Pediatrics*. <https://doi.org/10.1001/jamapediatrics.2019.3105>
- Suryadevara, M., Bonville, C. A., Cibola, D. A., Tomahawks, J. B., & Suryadevara, A. C. (2019). Associations between population-based voting trends during the 2016 US presidential election and adolescent vaccination rates. *Vaccine*, 37(9), 1160–1167. <https://doi.org/10.1016/j.vaccine.2019.01.036>
- Suryadevara, M., Bonville, C. A., Ferraioli, F., & Tomahawks, J. B. (2013). Community-centered education improves vaccination rates in children from low-income households. *Pediatrics*, 132(2), 319–325. <https://doi.org/10.1542/peds.2012-3927>
- Talking with Parents about Vaccines for Infants | CDC. (2019, April 1). <https://www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html>
- The Texas House of Representatives. (2007, April 5). *The official Website for the Texas House of Representatives. The Texas House of Representatives. Retrieved on April 5 2007 from http://www.legis.tx.us/tldocs/80R/billtext/doc/HB00215I.doc.* <http://www.legis.tx.us/tldocs/80R/billtext/doc/HB00215I.doc>
- Tomljenovic, L., & Shaw, C. A. (2012). Too fast or not too fast: The FDA’s approval of Merck’s HPV vaccine Gardasil. *The Journal of Law, Medicine & Ethics: A Journal of*

*the American Society of Law, Medicine & Ethics*, 40(3), 673–681.

<https://doi.org/10.1111/j.1748-720X.2012.00698.x>

Tribune, T. T. (2007, February 12). *Need to Hide Something Big?* The Texas Tribune.

<https://www.texastribune.org/texas-weekly/vol-23/no-32/need-to-hide-something-big/>

U.S. Department of Health and Human Services (DHHS), & National Center for Immunization and Respiratory Diseases (NCIRD). (2020). *The 2018 National Immunization Survey—Teen*. Centers for Disease Control and Prevention.

*Vaccination Coverage Rates: Department of Health*. (n.d.). Retrieved May 9, 2020, from

<https://health.ri.gov/data/vaccination/>

Vaccine Faces Scrutiny: Effectiveness against HPV, Cervical Cancer Questioned. (2007, May 10). *Grand Rapid Press*.

*Vaccines: Vac-Gen/Side Effects*. (2020, April 2). <https://www.cdc.gov/vaccines/vac-gen/side-effects.htm>

Wailoo, K., Livingston, J., Epstein, S., & Aronowitz, R. (2010). *Three Shots at Prevention: The HPV Vaccine and the Politics of Medicine's Simple Solutions*. JHU Press.

Wakefield, A., Murch, S., Anthony, A., Linnell, J., Casson, D., Malik, M., Berelowitz, M., Dhillon, A., Thomson, M., Harvey, P., Valentine, A., Davies, S., & Walker-Smith, J. (1998). RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet*, 351(9103), 637–641.

[https://doi.org/10.1016/S0140-6736\(97\)11096-0](https://doi.org/10.1016/S0140-6736(97)11096-0)

Walker, T. Y. (2017). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2016. *MMWR*.

*Morbidity and Mortality Weekly Report*, 66. <https://doi.org/10.15585/mmwr.mm6633a2>

- Walling, E. B., Benzoni, N., Dornfeld, J., Bhandari, R., Sisk, B. A., Garbutt, J., & Colditz, G. (2016). Interventions to Improve HPV Vaccine Uptake: A Systematic Review. *PEDIATRICS*, 138(1), e20153863–e20153863. <https://doi.org/10.1542/peds.2015-3863>
- Walters, E. (2019, August 12). *Texas almost mandated an HPV vaccine before politics got in the way. Now, the state has one of the country's highest rates of cervical cancer.* The Texas Tribune. <https://www.texastribune.org/2019/08/12/texas-low-rate-hpv-vaccination-keeping-cervical-cancer-rates-high/>
- Westbrook, L., & Fourie, I. (2015). A feminist information engagement framework for gynecological cancer patients: The case of cervical cancer. *Journal of Documentation*, 71(4), 752–774. <https://doi.org/10.1108/JD-09-2014-0124>
- WHO | *Safety update of HPV vaccines.* (n.d.). WHO; World Health Organization. Retrieved May 8, 2020, from [http://www.who.int/vaccine\\_safety/committee/topics/hpv/June\\_2017/en/](http://www.who.int/vaccine_safety/committee/topics/hpv/June_2017/en/)
- Williams, W. (2013). Noninfluenza Vaccination Coverage Among Adults—United States, 2011. *MMWR. Morbidity and Mortality Weekly Report*, 62(04), 66–72.
- Winer, R. L., Feng, Q., Hughes, J. P., O'Reilly, S., Kiviat, N. B., & Koutsky, L. A. (2008). Risk of Female Human Papillomavirus Acquisition Associated with First Male Sex Partner. *The Journal of Infectious Diseases*, 197(2), 279–282. <https://doi.org/10.1086/524875>
- Women in Government. (2011, November). *A Roadmap for Success: The State of Cervical Cancer Prevention in America 2010.* <https://www.womeningovernment.org/>
- Women in Government Report. (2008). *The 'State' of Cervical Cancer Prevention in America—2008: Turning Challenges into Opportunities.*

Zimm, A., & Bloom, J. (2006, May 26). Merck Promotes Cervical Cancer Shot by Publicizing Viral Cause. *Bloomberg News*.

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