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Vaccination Nation: A Bioethical Feminist Inquiry into the Political, Social and Ethical Controversy Surrounding the Human Papillomavirus Vaccine

Kirsten Keller Morin

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VACCINATION NATION: A BIOETHICAL FEMINIST INQUIRY INTO THE POLITICAL,
SOCIAL, AND ETHICAL CONTROVERSY SURROUNDING THE HUMAN
PAPILLOMAVIRUS VACCINE

by

KIRSTEN KELLER MORIN

(Under the Direction of Delores Liston)

ABSTRACT

This theoretical inquiry has explored the political, social, and ethical controversy surrounding the government's push to mandate the human papillomavirus (HPV) vaccine for adolescent girls. This vaccine has the potential of preventing cancer, specifically cervical cancer. There is a growing debate in this country whether this new HPV vaccine, Gardasil[®], should be added to the list of school-mandated vaccines.

Karen Houppert (2007) has stated that this particular "vaccine protects girls and women from cervical cancer and genital warts caused by the human papillomavirus (HPV)" (p. 17). So, what is the controversy? It all started with the fact that this vaccine is the first immunization produced to prevent cancer caused by a sexually transmitted disease (STD). There are several U.S. politicians that want to make the HPV vaccine a compulsory vaccine. Because an STD causes this disease there is a debate, according to Houppert, "by compassionate conservatives and abstinence-only hardliners who object to mandating the vaccine since the disease was the result of a lifestyle decision" (p.17). On the other hand, according to the Centers for Disease Control (CDC), "Gardasil[®] has proven 100% effective in preventing the four strains of HPV that are responsible for most cases of cervical cancer"(Manning, 2007, p. 11). So why not mandate it for adolescent girls? This question was explored further in this work using bioethical feminist

theory as a theoretical framework. This study was grounded in the works of Rosemarie Tong and Susan Sherwin.

INDEX WORDS: Bioethical Feminist Theory, Vaccine, Mandate, Cervical Cancer, Human Papillomavirus (HPV), Centers for Disease Control (CDC), Gardasil®

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by

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DOCTOR OF EDUCATION

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2009

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DEDICATION

First and foremost, this dissertation is dedicated to all the women who have lost their lives to cervical cancer. In writing this dissertation I have brought awareness to the readers about HPV and cervical cancer in hopes of preventing any more deaths from a very preventable disease.

Second, I have dedicated this piece of work to my mother, Sandy Keller, and my mother-in-law, Ella Morin, who were both life-long educators. They dedicated their lives to inspiring, nurturing, and teaching children and adults.

Third, I have dedicated this dissertation to my husband, Michael; daughters, Kellen and Kira; and son, Reece. The time I spent away from them as I pursued my doctorate is irreplaceable; but I hope I have made them proud with all I have accomplished over the last 3 years.

Last but not least, I have dedicated this inquiry to my father, Ulrich Keller. He has always been my role model and hero. I realize this sounds like a cliché, but it is the truth. He has shown me that hard work and integrity are the keys to success. He has also taught me to put others first, especially family. For this, I am truly thankful.

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This acknowledgement section, the last to be written, represents the finale to 3 years of hard work and long hours of research, reading, and writing. Writing this dissertation was the culmination and completion of many dreams for me, both personal and professional. It has represented a privileged opportunity, for which I have many people to thank.

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CHAPTER 1

INTRODUCTION

We live longer than we used to. No single medical advance had a greater impact on human health than vaccines.

-Paul A. Offit, M.D. (2005a, p. xi)

The year was 1855. A Massachusetts law was drafted that stated that all school-aged children must be vaccinated for the viral disease, smallpox, before they enter public school. This law was the beginning of the government's school mandated vaccination program. James Colgrove, a medical historian at the Columbia University Mailman School of Public Health, has stated, "School-based laws began in the 19th century, at about the same time as mandatory education laws...when people realized that schools were breeding grounds for illness" (Hendricks, 2007, ¶13). Today, in order for a person to attend most U.S. schools and colleges the individual state governments mandate several vaccines, like polio, measles, mumps, and rubella. Arthur Allen (2007) has asserted, "In America, vaccination is the first act the state requires of a person; without it, or legal exemption, a kid can't even get into nursery school" (p. 15). This "act" starts before an infant even leaves the hospital; at only 2 days old all infants born in the United States receive the Hepatitis B vaccine.

This 1855 compulsory vaccination order was also the beginning of a web of emotional, political, bioethical, legal, religious, and medical issues. The use of vaccines has been considered both controversial and beneficial to humankind. Vaccines have been touted as the eradicator of some of the deadliest diseases humans have ever encountered; they have also been accused of causing autism and poisoning our children with mercury, or as Marla Morris (2008) has stated, "Both poison and cure" (p. 28).

Jacob Heller (2008) has opined, “Aside from AIDS, most people have little or no first-hand contact with deadly epidemic disease” (p. 9); and today, there is a new vaccine at the forefront of use and contributing to the continued immunization dispute. This vaccine is the first of its kind because it is FDA approved to be administered to adolescent girls in hopes of preventing cervical cancer caused by the sexually transmitted human papillomavirus (HPV). In this bioethical feminist inquiry, I have explored the political, social, and ethical controversy that surrounds the government’s attempt to mandate the HPV vaccine for adolescent girls.

Context of Study

I can remember a few years ago sitting one warm summer evening watching the national news. The end story was about a new vaccine for women produced by Merck & Co. Pharmaceuticals. The vaccine was called Gardasil®. The newscast described Gardasil® as a vaccine that could provide immunity to certain types of cervical cancer and genital warts. The newscaster touted Gardasil® as a medical breakthrough in women’s health research, but it was not without controversy. At the time, I thought to myself, “How could this vaccine be controversial? This was the first cancer-preventing vaccine ever discovered, and better yet, it was produced just for women.” The controversy swirled around the fact that the government wanted to mandate the vaccine for adolescent girls. Parents were expressing discontent because this vaccine prevented cancer caused by HPV, a sexually transmitted disease (STD). From the time I heard this discordant story, I found my new passion, my course of study, or as Reynolds and Webber (2004) called it, my “line of flight” (p. 2). I decided that I wanted to research this vaccine and find out why it was being publicized as the new controversial immunization.

After doing the preliminary research, when presented with the information about the incidence of HPV and the efficacy of the HPV vaccine, I find it is hard not to argue that this

immunization is one of the best public health accomplishments for women in 50 years (Houppert, 2007). Jonathan Temte (2007), a professor at the University of Wisconsin School of Medicine and Public Health, has stated, “A medical intervention that is a true preventative tool and a good reason for anticipatory guidance and education does not come along often; the new HPV vaccine is both” (¶1). Unfortunately, the country is trapped in the controversy of mandating this vaccine instead of determining the best ways of making it affordable and accessible – both to U.S. girls and to those in developing countries who may never get the regular Pap smear exams they desperately need for early detection of cervical cancer.

The Political Context of the HPV Vaccine

The HPV vaccine debate highlights the balance between the government’s obligation to safeguard the health of its people and the rights of individuals to make their own decisions about matters affecting their health and their children’s health. All vaccine mandates pose this dilemma, but the question of an HPV vaccine presents more medical and ethical wrinkles. Unlike other contagious diseases, HPV cannot be spread by casual contact like a sneeze or cough. It is transmitted through close sexual contact. So mandating the HPV vaccine lacks the rationale that one student can be infected with HPV by sitting next to another student in the classroom. Under U.S. law, only the individual governing states, not the federal government, have the authority to mandate vaccinations, so the battle over HPV is being waged state by state. Currently, about 20 states and Washington, D.C. have proposed legislation that would require vaccinating all adolescent girls with the HPV vaccine (Savage, 2007).

The vaccine was developed and marketed by the well-known drug company Merck & Co., Inc. of Whitehouse Station, NJ. In June 2006, the Food and Drug Administration (FDA) approved Merck’s new vaccine called Gardasil®. Karen Houppert (2007) has stated that this

particular “vaccine protects girls and women from cervical cancer and genital warts caused by the human papillomavirus (HPV)” (p. 17). How can preventing cancer be controversial? Why are chicken pox or polio vaccines not making the nightly news or headlines in the local papers? It all starts with the fact that the vaccine is the first of its kind produced to prevent cancer caused by an STD. There are several U.S. politicians who want to make the HPV vaccine a compulsory immunization. Because an STD causes this disease, there is a debate, according to Houppert (2007), “by compassionate conservatives and abstinence-only hardliners who object to mandating the vaccine since the disease was the result of a lifestyle decision” (p.17). On the other hand, according to the Center for Disease Control (CDC), “Gardasil® has proven 100% effective in preventing the four strains of HPV that are responsible for most cases of cervical cancer” (Manning, 2007, p. 11). So why not mandate it for adolescent girls?

The American College of Pediatricians opposes requiring the vaccination for school attendance saying that such a mandate would represent “a serious, precedent setting action that trespasses on the rights of parents to make medical decision for their children as well as on the rights of the children to attend school” (O’Beirne, 2007, p. 20). One could apply this statement to all vaccines. The difference is that HPV is not transmitted by a cough or sneeze like polio, rubella, or the measles.

Currently, the Centers for Disease Control and Prevention (CDC) recommend that the HPV vaccine be administered to girls between the ages of 11 and 12. To be most effective in preventing HPV infection, the HPV vaccine would need to be administered before the onset of sexual activity. According to physician Shobha Krishnan (2008), “...nearly 50% of girls and boys are sexually active before graduating from high school” (p. 5). So it would be imperative to administer the vaccine to a girl before she reaches high school.

Currently, in today's political climate, if the government makes the HPV vaccine a mandatory immunization for all adolescent girls, there will be a backlash from parents, bioethicists, and civil rights advocates. A prime example of such a backlash occurred when Texas governor, Rick Perry, issued an executive order in February of 2007 that required all adolescent girls be vaccinated against HPV. The Texas House and Senate unanimously overturned the order in April of 2007 due to the hostile response of fellow politicians, civil rights groups, and Texas parents.

While many laws infringe on a person's rights, under the Constitution most states allow exemptions to the mandated vaccines. For example, 48 states allow exemptions for religious beliefs (Mississippi and West Virginia do not), 17 exempt for philosophical beliefs, and all states allow medical exemptions (Kohrs, 2002). Those claiming religious exemptions base their arguments on the right to free exercise of religion encompassed in the First Amendment of the U.S. Constitution. However, the U.S. Supreme Court has not recognized the First Amendment exemption to mandatory vaccination programs for infectious diseases (Kohrs, 2002). The U.S. Supreme Court states, "We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate" (Kohrs, 2002, p. 241). Philosophical exemption is based on an individual's objection to vaccines for personal, philosophical, moral, or other beliefs. The medical exemption requires a written declaration by a licensed physician stating the vaccination is dangerous to the individual's health. The final verdict for these three types of exemptions is left in the hands of the courts. Throughout history, the courts have, in matters of health, consistently put the common good before individual rights (Kohrs, 2002).

There is no question the compulsory vaccination policy is a violation of a person's right

to autonomy and privacy as stated by the Fourteenth Amendment of the U.S. Constitution, but we can thank vaccination policy for the complete eradication of smallpox, with polio not too far behind. It has also significantly reduced the incidence of several of the most devastating communicable diseases because of herd immunity. The HPV vaccine has the potential of offering herd immunity to men and women (Biedrzycki, 2007). Herd immunity describes a type of immunity that occurs when the vaccination of a portion of the population (or herd) provides protection to unvaccinated individuals. In diseases that can be passed from person to person, it is more difficult to pass that disease easily when there are those who are immune to it. Heller (2008) has asserted specifically on HPV:

The vaccination law applies to each individual in order to protect the larger community. The idea of herd immunity implies that any student who refuses to be vaccinated, then, risks more than her own health – she puts at risk the larger community’s ability to protect itself from an epidemic. (p. 11)

The more immune individuals there are, the less likely it is that a susceptible person will come into contact with someone who has the disease. We, as Americans, must realize in the matter of health and well being that the good of the many sometimes outweighs the interest of a few.

The Social Context of the HPV Vaccine

Mandating the HPV vaccine has been criticized not only by parents but also by family organizations, like Focus on the Family, abstinence-only hardliners, evangelical groups, and right-wing conservatives (Houppert, 2007; see also Daley & McDermott, 2007; O’Beirne, 2007). They are touting the familiar argument: Safe sex leads to more sex. Conservative California State Senator George Runner told the *Los Angeles Times* recently that he objected to the immunization because the disease was a result of lifestyle decisions, as opposed to a contagion (Houppert,

2007). Senator Runner went on to state, “Is there a more productive way for us to spend the money that may help someone who’s in a health situation that has nothing to do with their personal choices? Where do you want to focus your resources?” (Houppert, 2007, p. 17). Senator Runner has avoided extending this same argument to other lifestyle decisions, such as smoking or drinking alcohol.

Is giving a vaccine for a sexually transmitted disease tantamount to promoting sexual activity? This belief is not based on hard data and in fact has been disproved in studies examining contraceptive use and sexual activity. Douglas Kirby (2002) has stated, “There have been only four published studies of school condom-availability programs. All four of these studies found that making condoms available in schools did not significantly increase the rates of sexual activity in children” (p. 27). Still, abstinence programs such as True Love Waits and Brave Heart, primarily aimed at Christians, have produced limited but measurable results in lowering sexually transmitted infections rates, delaying sexual activity, reducing the number of sexual partners, and helping teens abstain until marriage. Religious faith does not guarantee protection from HPV. The sexual behavior of Christian teenagers is not all that different from that of their non-Christian peers (*Christianity Today*, 2007). According to researcher Mark Regnerus (2007) in his new book, *Forbidden Fruit: Sex and Religion in the Lives of American Teenagers*, “Evangelical teenagers don’t display just average sexual activity patterns, but rather above-average ones” (p. 119).

STDs have always served as a valuable tool for the abstinence lobby. HPV is especially handy because it can be contracted even when condoms are used. Of course, from a scientific perspective, there is no way to prove that inoculating girls against an STD will encourage promiscuity. However, Kelly Capes, an Oakland California mother, believes that having her

daughter immunized for HPV is sending the wrong message. Capes has stated, “I do not want my daughter to think I am condoning sex because I am immunizing her against a sexually transmitted disease” (Udesky, 2007, p. 979). Maurice Markman, the vice president for clinical research at the M.D. Anderson Cancer Center, has stated, “This is not about sex. This is about preventing cancer” (Atkinson, 2007, p. 56). Using the argument, “it will promote sex” is not a valid reason to deny immunizing adolescent girls. What if Merck had developed a vaccine that prevented lung cancer? Would the same people oppose it, claiming that it would encourage smoking? I go into further detail in regards to this argument in chapter 6.

The public must first be educated about the virus, the ways to prevent it, and the treatment options before the government starts playing big brother and mandating vaccines against sexually transmitted diseases. If parents are educated about the vaccine and its role in preventing cervical cancer, it is very likely of their own volition that they will choose to have their daughters immunized.

The Ethical Context of the HPV Vaccine

Mandating the HPV vaccine also raises ethical issues. Under current proposals, mandates would force people to undergo drug therapy (vaccination) when they have no disease, under the presumption that they might get a disease based on future behavior. One might argue that we do have, as public policy, mandatory vaccinations for some infectious diseases like mumps, measles, and rubella (MMR). The difference is that MMR are contagious diseases that can be caught by sitting next to an infected person in a classroom. HPV is not spread by casual contact.

Bioethical feminists have brought up another ethical issue at the forefront of the debate. Currently, the vaccine is gender-specific, recommended for girls only. The American Academy of Pediatrics does not support a school-linked mandate because “there are people who are

concerned about gender discrimination because it's a policy that would keep girls out of school and not boys, because it's a vaccine for girls" (Udesky, 2007, p. 980). Renee Jenkins, president-elect of The American Academy of Pediatrics, has stated, "Holding off on the mandate will give time for educating the public about the vaccine's benefits so parents do not feel like it is being shoved down their throats" (Udesky, 2007, p.980). Mothers and bioethical feminists look at the move to mandate the vaccine for girls but not boys as yet another example that women, not men, are made responsible for reproductive health (Houppert, 2007).

In the twentieth century, Oliver Sacks deemed L-DOPA, used on patients with *Encephalitis lethargica*, a "sort of medicine, of a wholly different kind: something deeper, older, extraordinary, almost sacred, which will restore to us our lost health and wholeness, and give us a sense of perfect well-being" (1973, p. 29). The HPV vaccine could be deemed the twenty-first century's extraordinary drug. Daley and McDermott assert, "One might assume that a well-documented, safe, and effective vaccine against the second leading cause of cancer death in women worldwide not only would be hailed as one of the greatest public health achievements, but also would be distributed with lightening speed" (2007, p. 178). Unfortunately, such accolade and action are not occurring. Some caution is necessary in any new achievement that affects public health however, this immunization program is linked to a sexually transmitted pathogen. With this being said, two questions come to mind. First, if this vaccine were approved for a virus that was non-genital, or not associated with sexual behavior, would we see delay in its deployment? Second, if this vaccine combated a virus that caused precancerous and cancerous conditions in boys and men only, would we be confronted with the same level of controversy and caution about its deployment? There is something fundamentally uncomfortable to Americans who might have to consider that adolescent girls will become sexually active and acquire a

sexually transmitted disease, which evokes emotion, discomfort and criticism (Daley & McDermott, 2007). Some women will die from this disease, and at least 70% of those deaths could be prevented through the administration of procedures similar to those that have eradicated smallpox and minimized the public health threat of polio and numerous other viral diseases. We must separate politics from science and begin an open dialogue on the best course of action for our children.

The Science Behind HPV, Cervical Cancer, and Vaccines

I would be remiss if I did not provide an overview of HPV, cervical cancer, and the science behind vaccines. These three subjects are discussed extensively throughout this paper, and an explanation of each of them is provided in this section of the inquiry.

What is the human papillomavirus (HPV)?

According to the Center for Disease Control, there are 45 million cases of undetected HPV in the United States, and current data indicate that 60 to 80 percent of people will be infected by HPV in their lifetime.

-Gregory Henderson, M.D. & Batya Yasgur

HPV is a species-specific and tissue-specific DNA virus that infects surface cells that cover the skin, mouth, esophagus, upper airways, urethra, anus, vagina, and the cervix (Fiander & Tristram, 2007; Henderson & Yasgur, 2002). Papilloma viruses have co-evolved with animal hosts over millions of years. HPV is made up of a collection of about 130 evolved viruses, 30 of which are passed via skin-to-skin sexual contact (Henderson & Yasgur, 2002). Of these 30, two cause 70% of cervical cancers (an additional 11 viruses are responsible for the rest), and 2 others cause 90% of genital warts (Atkinson, 2007). HPV is the most common sexually transmitted disease in the United States and generates about six million new infections a year (Biedrzycki,

2007). Henderson and Yasgur (2002) have stated, “Your chances of becoming infected or of already being infected with HPV are one in two” (p. 1). It has been estimated that 20 million Americans (both men and women) carry active infections at any given time. It is estimated that 75% of women will have some form of the virus during their lifetime (cited in Atkinson, 2007). Weinstock, Berman, and Cates (2000) state, “The young are especially at risk as nearly 75% of HPV infections occur in 15- to 24- year-old persons” (p. 6). Physician Jonathan Temte has stated, “Consequently, HPV infection is the most common sexually transmitted disease in American youth” (2007, p. 117).

HPV types 1 and 2 are responsible for producing benign skin warts, or papillomas, on the hands and feet. Warts are transmitted through casual skin-to-skin contact. A group of about 30 HPVs are transmitted through sexual contact and infect the anogenital region. There are no treatments to cure HPV infections, but for most women, the body’s defense system will clear the virus (Krishnan, 2008). Most HPV types that infect the genitals do not produce any noticeable symptoms (Krishnan, 2008).

Henderson and Yasgur (2002) have asserted, “A painfully unjust reality of HPV infection is that the majority of actual disease resulting from infection occurs in women” (p. 2). HPV types 6 and 11 cause genital warts and are considered “low-risk” for cervical cancer development. There are about 13 types that are classified as “high-risk” sexually transmitted HPVs, which include types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 (Fiander & Tristram, 2007). Cutts et al. stated, “Cervical cancer is estimated to affect approximately 500,000 women each year, of whom 80% live in developing countries” (2007, p. 719). Worldwide, 99.7% of cervical cancers are caused by high-risk HPV, and types 16 and 18 are responsible for 70% of all cervical cancers in women (Fiander & Tristram, 2007). These high-risk types not only lead to cervical

cancer, but also anal, vulvar, and penile cancer. Type 16 has been associated with oropharyngeal carcinoma, a form of head and neck cancer. Infectious diseases cause approximately one out of five human cancers (Ault, 2006). Cervical cancer is the second most common cancer in women, second only to breast cancer (Nicoletti & Tonelli, 2006). According to the National Cancer Institute (2007), 1 in 142 women will be diagnosed with cervical cancer during their lifetime.

Krishnan (2008) has asserted:

The virus invades the human body with great ease and then exerts a strong and permanent hold, bringing with it varying degrees of medical, emotional, and sexual upheaval. Its three-way threat – a silent infection, an incurable infection, and an infection that can cause cancer – can lead to tremendous emotional turmoil in many men and women. (p. 75)

With this being said, there is a tremendous disconnect between public awareness of the disease and the prevalence of HPV infection. This confirms the notion that the general propensity of our society is to avoid dialogue and education on any topic that can be considered taboo or personal by the political and religious institutions.

What is Cervical Cancer and How is it Detected?

Without him [Dr. Harald zur Hausen] there would have been no vaccine.

-Stephen Pincock

The 2008 Nobel Prize for medicine was awarded to a German scientist who discovered that HPV causes cervical cancer (Pincock, 2008). The scientist responsible for the discovery is a German native named Harald zur Hausen. Physician Diane Harper from the Dartmouth Medical School in New Hampshire has stated, “His [Hausen] methods were thorough, detail oriented, following scientific rigor through every subsequent question he postulated and answered about

the biological relationship between HPV and cervical cancer” (Pincock, 2008, p. 1375). From Dr. zur Hausen’s work, it became medically accepted that HPV was the causative agent of cervical cancer.

After breast cancer, cervical cancer is the most common cancer found in women (Hughes, 2009). The cervix is located at the base of the uterus. It has two functions: (a) to keep bacteria and viruses out of the uterus; and (b) to keep fetuses securely in the uterus until they are ready to be born (Henderson & Yasgur, 2008). Cervical cancer is caused when cells of the cervix are attacked by certain strains of HPV. The cells of the cervix begin to grow and divide uncontrollably. Normal cervical cells are pushed aside by these rapidly dividing cells, which start to pile up on each other (Henderson & Yasgur, 2008). If this uncontrollable cell division goes unchecked, then the cancerous cells can penetrate the bloodstream and lymphatic system causing the cancer to proliferate throughout the body. A sexually active woman’s best defense against cervical cancer caused by all “high-risk” or virulent strains of HPV is an annual gynecological exam called the Pap smear (Krishnan, 2008).

The Pap smear or Papanicolaou test is a medical screening method that has been used since the 1940s to detect cervical cancer and other uterine abnormalities. Katz and Wright (2006) state, “The Pap smear had transformed cervical cancer from a leading killer to a rare disease in the United States” (p. 1110). Physician George Papanicolaou, a Greek cytologist, whose specialty was early cancer screening and detection, developed the Pap smear. While this technology is widely available and has reduced cervical cancer incidence in industrialized nations, it is not readily available in third world nations in which cervical cancer incidence and mortality is high (Brinkman, Caffrey, Muderspach, Roman, & Kast, 2005). In many developing countries it is the leading cause of cancer death among women (Siddiqui & Perry, 2006).

The development of HPV-induced cervical cancer is a slow process that can take many years to develop. During the developmental phase, dysplasia (precancerous cells) of the cervix can be detected. During a Pap smear a sample of exfoliated cells is taken from the opening of the cervix (Brinkman et al., 2005). Once the cells are collected, a pathologist stains and examines them for the presence of koilocytosis (Brinkman et al., 2005). Koilocytic cells have a distinctive abnormality in their appearance in which some of the nuclei in the cells are surrounded by tiny "halos" (Military Gynecology and Obstetrics, 2005). Most commonly, these changes occur in the presence of HPV, but occasionally are associated with more serious problems such as cervical dysplasia or even early cellular malignancy. The Pap smear is 85-95% effective in detecting koilocytic cells (Brinkman et al., 2005).

The American College of Obstetricians and Gynecologists, the American Cancer Society, and the U.S. Preventive Services Task Force recommend that women should get their first Pap smear no later than 3 years after their first sexual encounter and no later than 21 years of age (U.S. Department of Health and Human Services, 2006). Women should have an annual Pap smear until the age of 30 (U.S. Department of Health and Human Services, 2006). After 30, women should discuss with their doctors how often a Pap smear should be done.

Cervical screening has reduced the incidence of cervical cancer deaths by 70% over the last 50 years. In the U.S., approximately 60 million women receive a Pap smear each year, which results in the diagnosis of 1.25 million women with pre-cancers (Siddiqui & Perry, 2006). However, Nicoletti and Tonelli (2006) have stated, "On average, there are about 9,710 new cases of cervical cancer in the United States each year and 3,700 deaths are attributed to it" (p. 423). The lethality of cervical cancer is even greater worldwide, causing over 470,000 new cases each year and 233,000 deaths (Nicoletti & Tonelli, 2005). The discrepancy is largely due to the

decreased availability of affordable screening and treatment in many countries. According to Franco and Harper (2005), Eastern and Southern Africa have the highest incidence and mortality of HPV in the world.

Few countries have the resources and infrastructure necessary to run organized screening programs, so the poorest regions of the world bear the brunt of the disease. Most women in low-income countries do not have access to routine screening: only 5% have undergone a Pap smear in the past 5 years (Katz & Wright, 2006). In parts of Latin America and the Caribbean, more women die from cervical cancer than from complications of childbirth (Population Reference Bureau, 2006).

The Container for the Thing Contained – The Definition of a Vaccine

So, what defense do women have against an HPV infection? The first line of defense is the woman's own immune system. In humans, lymphocytes, or white blood cells, wage war on pathogens like viruses. The immune system is a complicated network of cells that work together to fight foreign invaders and can provide continual immunity from future attacks. This second line of defense is acquired immunity from certain viral infections that come in the form of a vaccine.

Arthur Allen (2007) has defined a vaccine as, "A substance that introduces a whole or partial version of a pathogenic microorganism into the body in order to train the immune system to defend itself when the organism threatens to cause an infection through natural means" (p. 14). A vaccine works by stimulating the immune system to create antibodies and immune cells that recognize the pathogen and are thus prepared to battle it when it presents itself at the portals of the body. In this sense, those that receive vaccinations contribute to our posthuman future.

Vaccines enhance normal immunological function by modifying the reactivity time of the immune system when it comes into contact with a foreign entity. From a scientific perspective, vaccination has evolved from a purely experimental procedure into a biotechnology that benefits from our growing ability to understand and manipulate microorganisms and our immune systems. Nicholas Agar (2007) has asserted, “The universal value of preventing and curing disease is not inconsistent with valuing humanity. There is nothing spookily posthuman about someone reaching old age without succumbing to [cervical] cancer” (p. 16). Katherine Hayles (1999) has stated, “The posthuman view thinks of the body as the original prosthesis we all learn to manipulate, so that extending or replacing the body with other prostheses becomes a continuation of a process that began before we were born” (p. 3). Vaccines can be seen as immunological prostheses that allow us to endure in a world filled with life threatening pathogens.

The use of vaccines has saved millions of lives and even eradicated certain diseases like smallpox and polio. Nevertheless, vaccines have been the center of controversy ever since Edward Jenner, the scientist who discovered the smallpox vaccine, scraped pus from the sore of a dairymaid infected with cowpox into an incision on a healthy boy’s arm. This event marked the birth of the smallpox vaccine, and the beginning of vaccinology.

The Development of the HPV Vaccine

The FDA approved the HPV vaccine, Gardasil[®], on June 8, 2006. Currently Gardasil[®] is the only FDA approved HPV vaccine available. A second HPV vaccine, Cervarix[®], produced by GlaxoKlineSmith, is in Phase III clinical trials and has not been approved by the FDA for distribution in the United States. Gardasil[®] is the first vaccine approved to target the HPV types (6, 11, 16, and 18) that are associated with the development of 70% of the cases of cervical

cancer and 90% of the cases of genital warts (Krishnan, 2008). Medical and public health professional associations have endorsed the vaccine, including the American College of Obstetrics and Gynecology, the American Academy of Pediatrics, the Society for Adolescent Medicine, and the American Cancer Society (Daley & McDermott, 2007). Nearly 2 decades ago, researchers at the National Cancer Institute (NCI), part of the National Institutes of Health, and other institutions began searching for the underlying causes of cervical cancer. The vaccine is based on the work of physician Douglas Lowry and his colleague John Schiller. Lowry is the laboratory chief of the National Cancer Institute Laboratory of Cellular Oncology. About 20 years ago, Lowry began working with Schiller on a vaccine for HPV. Lowry said the idea came to him after attending a lecture on hepatitis B virus vaccine. Lowry's goal was to produce HPV particles that could elicit a strong neutralizing antibody response, a method that had worked previously in the development of hepatitis B vaccines. "Most preventative vaccines depend on serum neutralizing antibodies," Lowry has stated (cited in Traynor, 2007, p. 452). A serum neutralizing antibody is a form of antibody that reacts with an infectious agent (usually a virus) and destroys or inhibits its infectivity and virulence; it may be demonstrated by means of mixing serum (protein-rich liquid that separates out when blood coagulates) with the suspension of infectious agent, and then injecting the mixture into animals or cell cultures that are susceptible to the agent in question.

Genetic engineering, technology involving the manipulation of genetic material, was used to create this vaccine. A postdoctoral fellow in Lowry's laboratory discovered that the L1 structural protein of bovine papillomavirus, an HPV cousin, could be produced in insect cells and would interact with another structural protein to "self-assemble" into human papillomavirus-like particles minus the pathogenic agent. The L1 protein induced high levels of neutralizing

antibodies in an animal model system, a critical step in potential vaccine development. Lowry has stated, "These hollow spheres, formed by a single protein from the virus (L1 protein), trigger an antibody response that is capable of protecting the body against infection by the targeted virus types" (National Cancer Institute, 2006, ¶3).

Because the National Institutes of Health (NIH) perform basic research but do not develop finished drug products, Lowry said his group "tried to engage different pharmaceutical companies to work with us" to produce a marketable vaccine" (cited in Traynor, 2007, p. 452). Merck and MedImmune were the first takers, and the companies conducted their own experiments to prove the technology worked. NIH eventually licensed the technology to those companies, and GlaxoSmithKline later became involved through a sublicense from MedImmune. "Future improvements, such as expanding the number of HPV strains in the vaccine, can make the next-generation product even better," Lowry has stated, adding that he expects Merck and GlaxoSmithKline to take this approach (cited in Traynor, 2007, p. 452).

Lowry has asserted, "Although critical early HPV vaccine research was conducted at NIH, the story of the efficacy of the vaccine really is the story of the pharmaceutical companies and not the story of the NIH" (cited in Traynor, 2007, p. 452). This statement is an example of biocapital at work. Kaushik Rajan (2006) has stated that biocapital is:

... concerned with tracking and theorizing the co-production of an emergent technoscientific regime – that of biotechnology in the context of drug development – with an emergent political economic regime that sees the increased prevalence of such research in corporate locales, with corporate agendas and practices. (p.78)

The U.S government spends an enormous amount of money on biomedical research which is funded through the NIH (site of Lowry's laboratory) "consequent to the declaration of a war on

cancer in the early 1970” (Rajan, 2006, p. 6). The government’s research was then used by Merck to develop and patent the blockbuster vaccine. The use of the government’s research to produce a drug for commercial sale is allowed through the 1980 Bayh-Dole Act. Rajan (2006) states, “...The 1980 Bayh-Dole Act, [is] legislation that facilitates the transfer of technology between academe and industry and thereby enable[s] rapid commercialization of basic research problems” (p. 6). The NIH performed the preliminary research and because they do not have the ability to produce finished drug products they licensed the technology to Merck. Merck is making billions of dollars based on the original research produced by a federal government laboratory, specifically the NIH. Currently, Merck is charging the government roughly \$360 per vaccination (most other recommended vaccines cost less than \$50) given to girls on Medicaid and the Vaccines for Children program. Marcia Angell has called this a “real scandal” (2005, p. 56). Merck is banking billions of dollars on publicly funded research. It seems to me that Merck is “double-dipping” – in terms of not only benefiting from government research to make a very expensive drug; it is profiting from the government every time a child on Medicaid and the Vaccines for Children Program is vaccinated.

Gardasil® was evaluated and approved in 6 months under the FDA’s priority review process – a process for products with potential to provide significant health benefits. The priority review process must have made Merck very happy, because according to Marcia Angell (2005), “Clinical trials usually take a few years, and during that time the drug cannot be sold. That means clinical testing eats into a drug’s twenty year patent life—the time it can be sold without competition” (p. 28).

Gardasil® is given as three intramuscular injections over a 6-month period, costing \$120 per injection. According to Dr. Neil Goodman, a pediatrician who offers the vaccine, “the actual

cost of a single injection is closer to \$175 when you factor in the excise tax, storage and handling, and the office costs of administering the vaccine” (personal communication, July 3, 2007). Gardasil® is currently the most expensive pediatric vaccine (Snow, 2007). The vaccine has been approved for females ages 9 to 26, and currently the CDC recommends that all 11-or 12- year old girls be immunized. The vaccine works best if given before the female is sexually active.

Women are not protected if they have been infected with the HPV types prior to vaccination.

Gardasil® was evaluated and approved in 6 months under the FDA’s priority review process – a process for products with potential to provide significant health benefits. The priority review process gives Merck an advantage, because according to Marcia Angell (2005), “Clinical trials usually take a few years, and during that time the drug cannot be sold. This means clinical testing eats into a drug’s twenty year patent life—the time it can be sold without competition” (p. 28). For the last 3 years, Merck has had a monopoly on the HPV vaccines approved in the U.S. On September 9, 2009 an advisory panel of the FDA voted that research data from GlaxoSmithKline pharmaceuticals’ version of the HPV vaccine, Cervarix®, demonstrated safety and efficacy. Cervarix® is currently marketed in 100 countries and is waiting for final approval by the FDA to market it in the U.S.

Four studies, one in the United States and three multinational, were conducted on 25,000 women ages 16-26 by giving them either the vaccine or an inactive injection (placebo). In women who had not already been infected with HPV, Gardasil® was nearly 100% effective in preventing pre-cancerous cervical lesions, pre-cancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed (Siddigui & Perry, 2006). The women were followed for 2 years, and while the study period was not long

enough for cervical cancer to develop, the prevention of these cervical pre-cancerous lesions is believed to result in the prevention of those cancers. Currently, it is believed that the vaccine has efficacy for 5 years, after that a booster shot may be required (Siddiqui & Perry, 2006).

Gardasil® works by inducing a strong humoral immune response, which involves the body producing specific antibodies to fight disease. The vaccine consists of a mixture of four types of DNA-free virus like particles derived from the capsid proteins of HPV types 6, 11, 16, and 18 (Siddiqui & Perry, 2006). The capsid of a virus forms an envelope or shell around the genetic material. In order for a virus to replicate, it must attach to a host cell, in this case a cervical cell, and inject its genetic material (DNA) into the host cell. The genetic material of the virus takes over the machinery of the host cell in order to carry out viral DNA replication and production of multiple copies of the capsid protein subunits. The viral components, DNA and capsid proteins, begin to assemble themselves into new viruses. Once the host cell becomes full of newly assembled viral particles, it bursts open releasing hundreds or thousands of new viruses that are ready to attack other host cells. The cervical cells die as a result. When a person is immunized with Gardasil®, the immune system recognizes the particles in the vaccine as foreign, destroys them, and forms antibodies against HPV types 6, 11, 16, and 18 (see Figure 1). When an immunized person comes into contact with HPV 6, 11, 16, and 18, the body's immune system recognizes the virus and destroys it before it can infect cervical cells.

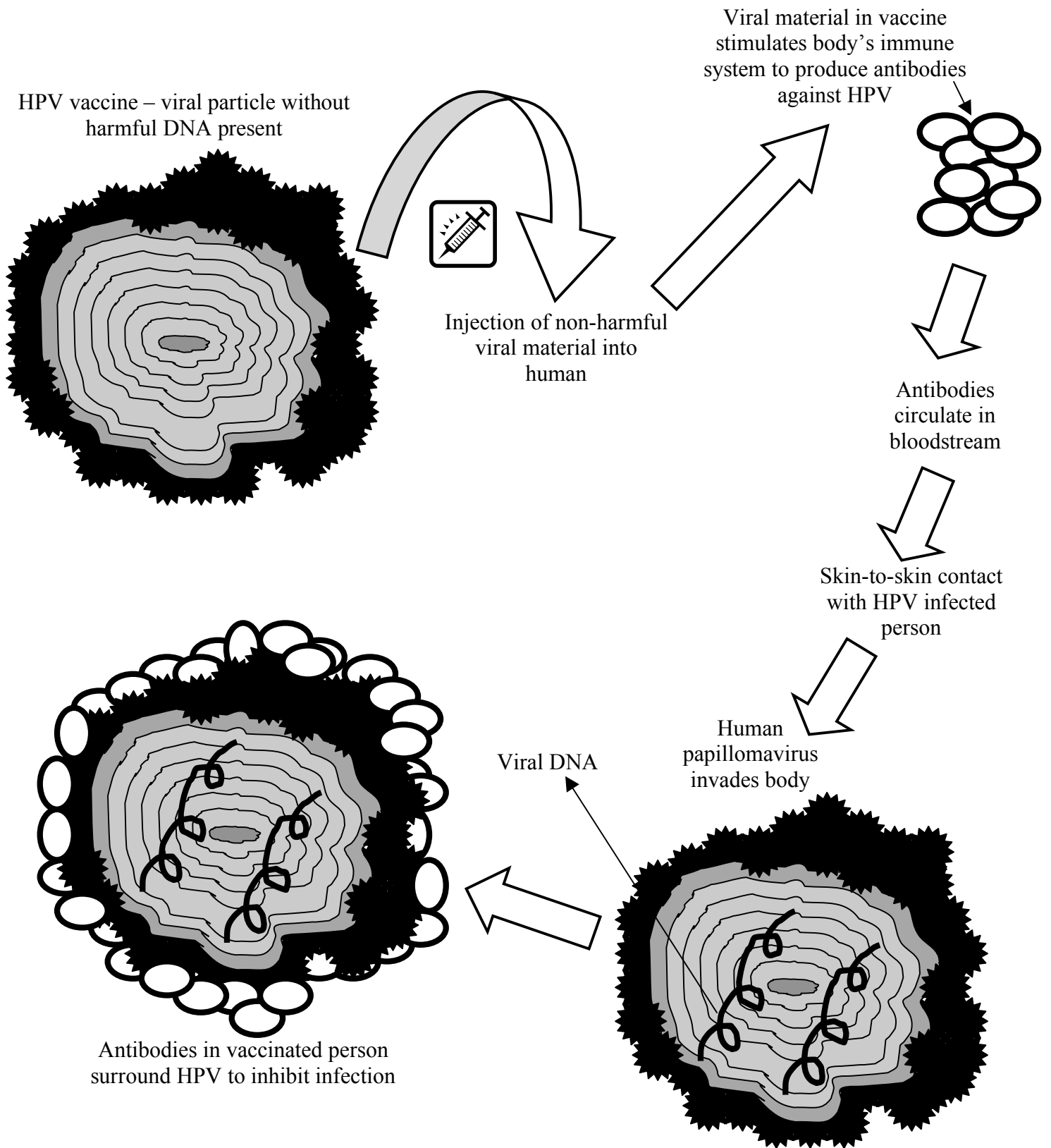


Figure 1. An illustration of the effects of immunization against HPV.

Statement of the Problem

How can a medical breakthrough for women be controversial? How can a vaccine for a type of cancer that kills more than 300,000 women worldwide be controversial? Both doctors and patients want marvels in modern medicine to be unambiguous and uncomplicated. Unfortunately, in a complex field such as medicine, the potential benefits or perils of new discoveries are seldom seen in black and white. When a new drug is introduced into the market, some welcome it with open arms while many are skeptical. Vaccines are no exception. Kurt Link (2005) has stated, “Vaccination is more than 100 years old and has been controversial from the start. Of all the benefits of medical science, vaccination is at or near the summit. It is also the most controversial of routine medical procedures” (p. 38).

There are obstacles inherent in the science of vaccinology, but the field has special societal obstacles: fear of the unknown, of mandates, of a highly litigious environment, bureaucracy, self-serving politization, political turf wars, a very powerful pharmaceutical industry, and irrational policy decisions. Every new vaccine brings new controversies – the HPV vaccine is a prime example. The scientists manipulating the genes of pathogens are exploring the essence of life, and we can only wonder what new wonders and new grief they will find. My study uncovers the complex layers of political, social, and bioethical controversies surrounding the HPV vaccine. My goal in undertaking this inquiry has been to analyze each of these layers in order to help all those confronted with the HPV vaccine controversy make a well-informed decision about the immunization and its effectiveness.

The Purpose of the Study

“You have to admire its simplicity. It's one billionth our size and it's beating us” (Henderson, Kopelson, Katz, & Peterson, 1995). This quote came from the 1995 movie,

Outbreak, about how fast a virus can mutate and spread throughout a human population. Viruses are bits and pieces of protein and nucleic acid. Not fitting into any of the six taxonomic kingdoms, biologists do not classify them with all other carbon-based organisms. However, they are a part of our biosphere that has wreaked havoc since the “fall of man.” Viruses can be defined as nonliving parasitic entities that use the cells of other organisms to reproduce. Viruses invade and infect a host taking over cellular organelles for their own survival and procreation. They are silent, they can be deadly, and they have the ability to mutate to survive in almost any environment. Their evolution has produced over 5000 different strains, and viruses are responsible for diseases like smallpox, chicken pox, influenza, acquired immune deficiency syndrome (AIDS), ebola, rabies, yellow fever, polio, mumps, measles, rubella, common cold, avian flu, herpes simplex I and II, severe acute respiratory syndrome (SARS), and some types of cancer (Allen, A., 2007; Koplow, 2003).

This discussion of this miniscule anomaly is the focus of this study. To conduct it, I have investigated the history, medical, and political/social controversy that surround the virus and its vaccine. I specifically focused on the HPV vaccine called Gardasil®. Gardasil® is the first anti-cancer vaccine of any kind approved for human use (Daley & McDermott, 2007).

My intention for undertaking this inquiry was to educate women and adolescent girls on one of the most widespread sexually transmitted diseases in the United States. I will take an in depth look at HPV and its vaccine. I investigated the health curriculum in U.S. schools and found a lack of proper education when it comes to sexually transmitted diseases. Having taught health to high school students, I have firsthand experience with the lack of emphasis placed on educating students about sexually transmitted diseases. Most of the emphasis is placed on drug and alcohol abuse. Educating young adolescent girls about sexually transmitted diseases is

paramount to preventing the spread of HPV. The Georgia health curriculum stresses abstinence as the best prevention against sexually transmitted diseases. This is true, but as educators we must be realistic. Not all adolescents are going to refrain from sex until they are married. According to Shobha Krishnan, an obstetrician and gynecologist, “Thirteen percent of American teens are sexually experienced by the time they are 15 years old, and 70 percent are sexually experienced by 19 years of age” (2008, p. 151).

Research Questions

The primary research question examined in this theoretical inquiry was “Why is there a contentious debate in the U.S. over mandating the first vaccine developed to prevent cancer?” The secondary questions that were addressed are:

- (1) What are the political ramifications of the U.S. government mandating the HPV vaccine for adolescent girls?
- (2) What are the social and the ethical controversies behind the drug company Merck’s introduction of Gardasil[®] for adolescent girls and not boys?

Autobiographical Roots of My Inquiry

From the small boy with a scraped knee to an elderly women fighting breast cancer, everyone has a pathography. Bioethical feminist Rosemarie Tong (2000) has written, “Because all human beings have bodies, minds, and spirits, all human beings are capable of feeling pain and experiencing suffering” (p. 27). Everyone has a story about illness, disease, or injury. But according to Virginia Woolf (1930), “...it becomes strange indeed that illness has not taken its place with love and battle and jealousy among the prime themes of literature” (pp. 3-4). Why are we hesitant to talk about our illnesses? Is it because we realize we are only human? Is it that we realize that death is inevitable? Bernard Miall (1920) has acknowledged, “What makes for the

fullness and perfection of life, for beauty and happiness, is good; what makes for death, disease, imperfection, suffering, is bad” (p. 244). Society often regards the ill person as useless and devoid of worth. Arthur Kleinman (1989) described illness as “the seemingly relentless march toward becoming an invalid” (p. 35). Unfortunately, I have had some personal experience with HPV and abnormal cervical changes. My autobiographical roots are embedded in a form of inquiry called pathography – a story of illness.

There is often a stigma placed on the ill body. Marla Morris (2008) has stated, “In some cases, the easiest way to approach the illness of another is to blame the victim. ‘It must be your fault, you did it to yourself’” (p. 3). A person with Hepatitis C may be accused of being a drug abuser, or a person who has heart disease may be blamed for having a poor diet. We often look to blame the person for their illness, for it seems we must find fault somewhere. Why not the person with the illness? They brought it upon themselves, right? They caused their illness. Susan Sontag (1977) has asserted, “Patients who are instructed that they have, unwittingly, caused their disease are also being made to feel that they have deserved it” (p. 57). No one “deserves” to be ill. Unfortunately, illness is part of life and is something that binds us all as human beings. We all get ill sometime in our lives. Sontag (1977) eloquently has expressed:

Illness is the night-side of life, a more onerous side of citizenship. Everyone who is born owns dual citizenship, in the kingdom of the well and the kingdom of the sick. Although we all prefer to use only the good passport, sooner or later each of us is obliged, at least for a spell, to identify ourselves as citizens of that other place. (p. 3)

It is when we take the passport to the “other place” that pathography is born.

When Ill Bodies Need Voices – The Definition of Pathography

-Stories are antibodies against illness and pain.

Anatole Broyard

This section focuses on the meaning of pathography as a piece of literature and a form of narrative inquiry. Our personalities and our identities are intimately bound up with the stories that we tell to organize and to make sense of our lives. To understand the human meaning of illness, we therefore must turn to the stories we tell about illness, suffering, and medical care. Anne Hunsaker Hawkins (1999a) has defined pathography as, "...a form of autobiography or biography that describes personal experiences of illness, treatment, and sometimes death" (p. 1). Pathographies characterize questions like "what is it like to be diabetic" or "what it means to have cancer." These stories of illness can provide the reader with direct insight into the realm of pain and suffering.

Pathographies have many functions. They not only articulate fears, hopes, and anxieties about illness, but they also serve as a roadmap to the medical experience as a whole. Anne Hunsaker Hawkins (1999b) has noted, "Pathographies are a veritable goldmine of patient attitudes and assumptions regarding all aspects of illness" (p. 127). Pathographies can also provide an outlet of expression for the ill person. Anatole Broyard, an American literary critic, wrote a pathography about his battle with prostate cancer. Broyard (1992) called his pathography a type of "literary aspirin" (p. 18). He believed that a patient should not sink into depression, but treat his or her illness as a narrative. He has stated, "Anything is better than an awful silent suffering" (1992, p. 20).

Pathography is a type of narrative inquiry and is often called illness narrative. Michael Connelly and D. Jean Clandinin (1991) often refer to narrative inquiry as a "storied experience"

(p. 121). Narrative is a form of expression recognizable as a story of “discourses with a clear sequential order that connect events in a meaningful way” (Elliott, 2005, p. 26). The telling of stories is an integral part of human social communication – occurring in all types of textual, verbal, nonverbal, and creative expressions – as a means to describe, reflect, share, perform or entertain (Ricoeur, 1984). Storytelling in general, appears to be sparked by experiences of a breach or disruption, however minor, in our usual patterns of life. Stories, therefore, gain a particular relevance at times of life transition or change, seemingly as a way of sense making or attempting to reshape and manage the shifting ground of our lives. In a pathography, the time of transition or change comes in the form of an illness. Anatole Broyard (1992) has stated, “The patient has to start by treating his illness not as a disaster, an occasion for depression or panic, but as a narrative, a story” (p. 20).

An illness represents a major instance of “biological disruption” (Bury, 1982) where balance between the body, mind, and everyday life are threatened. The study of illness narrative is an exploration of this disrupted experience, as well as its meanings and the actions related to dealing with it. Marla Morris (2008) has written, “Making the best of illness means writing about it so that others might learn about what it means to be sick” (p. 5). Cheryl Mattingly noted that the suffering of illness and facing death tends to demand a story. Mattingly (1998) has stated, “It is the one liminal place within the human condition that calls for sense making and this often takes narrative form” (p. 1).

Types of Pathography

According to Anne Hunsaker Hawkins, pathographies can be divided into four distinct categories: Testimonial pathographies, angry pathographies, “pathographies advocating alternative modes of treatment” (1999a, p. 4), and ecopathography. Testimonial pathographies,

also called didactic pathographies, are narratives motivated by the explicit wish to help others. Often they blend practical information with a personal account of the experience of illness and treatment. Hawkins (1999a) states, “Pathographies written with an overtly didactic intent blend a personal account of illness with practical information” (p. 4). For example, descriptions of breast cancer experience have enabled women to become aware of therapeutic alternatives both within and outside conventional medical practice. A prime example of this type of pathography is Marilyn Snyder’s *An Informed Decision*, a book written for women with breast cancer who might be helped by surgical reconstruction. Another example of this type of pathography is the actress and comedian Gilda Radner’s book, *It’s Always Something*, on her battle with ovarian cancer.

The second type is the angry pathography. Authors of this type are motivated by a strong need, based on personal experience, to point out deficiencies in various aspects of patient care. Hawkins (1999a) has opined:

Angry pathographies are intended to expose and denounce atrocities in the way illness is treated in America today. These books testify to a medical system out of control, dehumanized, and sometimes brutalizing; and they are written from a sense of outrage over particular and concrete instances of what is perceived to be the failure of medicine to care adequately for the ill. (p. 6)

Pathographies of this kind are important in alerting all of us to important problems in medical practice. They vividly depict how an ill person today can be at the same time the beneficiary and the victim of a healthcare system whose very excellence – its superb technological and pharmacological achievements – is at the same time potentially dehumanizing.

The third type of pathography is called the “alternatives pathography.” This type of illness narrative is also critical of our medical system, but without angry criticism and doctor bashing. These pathographies stem from dissatisfaction with medicine. They differ in that the author is concerned not so much with criticizing traditional medicine as with finding alternative modes of treatment. One can find a pathography about every conceivable kind of alternative to traditional medicine (Hawkins, 1999a). This group of pathographies can be invaluable in alerting doctors to the appeal of alternative medicine and to the specific treatments that attract patients with particular illnesses.

The fourth type is called ecopathography. This type links personal experience of illness with larger environmental, political, or cultural problems. Illness is perceived as the product of a toxic environment. This type of pathography is used to warn us that a person’s illness is a sign and symptom of much larger problems confronting our culture as a whole. An example of this type of pathography is Terry Tempest Williams’ narrative *Refuge: An Unnatural History of Family and Place*. In Williams’ book, she discussed the death of her mother from cancer at the age of 44. Williams revealed her concern with the implication of environmental pollution in the various cancers in the last several generations of women in her family. She revealed that she grew up in an area that practiced above ground nuclear testing.

The common denominator of all pathographies, whatever the perceived motives of their authors, is that the act of writing in some way seems to facilitate recovery and the healing of the whole person. Serious illness is a painful, disorientating, and isolating experience. It is a trauma, an insult not only to the body, but also to the self. Arthur Frank (1991) has stated, “What happens to my body happens to my life” (p. 13). Writing about an illness experience is a kind of

psychic rebuilding that involves finding patterns, imposing order, and discovering meaning (Lifton, 1967). Pathography is not only a description of how awful it is to be seriously ill, but also a testimony to the capacity to transform that experience in ways that heal. Audre Lorde reiterated this sentiment in her book called *The Cancer Journals*. Her motivation for writing her pathography is to teach women what she knows about life through her experience with breast cancer. Lorde (1997) wrote, "...it is necessary to teach by living and speaking those truths which we believe and know beyond understanding. Because in this way alone we can survive, by taking part in a process of life that is creative and continuing, that is growth" (p. 21).

The Historical Roots and Traditions of Pathography (Illness Narrative)

The historical advancement and sovereignty of science brought with it a culture that valued a more rational and detached approach to the world. Science and technology also introduced a sea of change in the role of medicine and healing, as well as the relationship of healer and patient. Illness is a time of personal crisis that compels individuals to re-assess and rewrite their private narrative, in an attempt to create a sense of continuity in the pre and post sickness identity. Sander Gilman (1988) has stated, "For illness is a real loss of control that results in our becoming the Other whom we have feared, whom we have projected onto the world" (p. 2). It is in the state of being the Other that the illness narrative is written. Traditionally, the illness narrative was a part of the healing process. Prior to the appearance of a more bio-technological medical model, the importance of the patient's story was the central feature around which the healing intervention focused. This was especially true in the seventeenth and eighteenth centuries before the discovery of antibiotics, when medical interventions primarily centered on procedures such as bleeding and purging as a way to restore "one's bodily humors and equilibrium"

(Lawrence, 1994). As stated by Roy Porter (1997) in his historical overview of medicine, “In the absence of decisive anatomical or physiological expertise, and without a powerful arsenal of cures and surgical skills, the ability to diagnose and make prognoses was highly valued, and an intimate physician-patient relationship was fostered” (pp. 9-10). This relationship was to become greatly altered with the introduction of modern medicine and its reliance on science and the technological advances of biochemistry. The healer’s focus shifted from the patient as a key figure in diagnosis and understanding of disease, to patient as a supplier of biological material that would be submitted to a laboratory for final analysis and evaluation. David Morris (2000) went as far to say, “Doctors are authorities on disease, while patients remain the more or less unreliable narrators of their own unruly illnesses” (p. 38).

The objective of health care evolved from bringing the body to the individual patient’s healthy “natural state” to curing or repairing. Mike Bury (2001) has stated:

The task of the doctor, increasingly in the 19th and into the 20th century, was to translate pieces of information into a definitive diagnosis that linked the disease to specific biological causes and outcomes, rather than to the patient’s circumstances or lifestyle, let alone to their beliefs or values. (p. 266)

This had political ramifications, impacting the practice of modern medicine and its growing precedence in the healing arts. According to Christopher Lawrence (1994), “...by 1920 the idea of disease as individual pathology had become the dominant paradigm and was extricably linked to the development of a ‘bounded’ medical profession, that exerted almost complete jurisdiction over illness and its treatment” (p. 27). The acceleration of this process in the 1940s and onward only seemed to reinforce the tendency to render the patient passive (Bury, 2001). As illness was

increasingly sequestered from everyday life by professional medicine, so the patient's suffering was effectively silenced, especially under the impact of modern medicine and technological advancement. Talcott Parsons (1951) further described this in his treatise of the "sick role," stating that the patient's responsibility in illness becomes one of simple compliance as the physician's allegiance become connected to the scientific code of medicine rather than the individual. Arthur Frank (1995), describing the modern experience of illness, stated:

...when the popular experience is overtaken by technical expertise, including complex organizations of treatment. Folk no longer go to bed and die, cared for by family members and neighbors who have a talent for healing. Folk now go to paid professionals to reinterpret their pains as symptoms, using specialized language that is unfamiliar and overwhelming. (p.5)

And it is the medical narrative, the one told by the physician, which prevails and takes precedence over all other narratives. As Frank (1995) has asserted, "The story told by physicians becomes the one against which others are ultimately judged true or false, useful or not" (p. 5). Is it any wonder that the meaning that we create about our illness, and its impact on our life, is often the essential but silent element in the patient-doctor interaction? Marla Morris (2008) has contended, "The narratives that sick people tell – especially stories that women tell – tend to be discounted by the medical community. It is thought that the sick are unreliable narrators" (p. 6).

However, spanning a decade or more, various factors have come into play that create pressure on this technological, bio-medical model of healthcare, shifting the pendulum back towards a consideration of patient narrative. As stated by Bury (2001) and Kleinman (1989), the

first of these is the growing impact of degenerative and chronic illness. As the population ages and health care providers are increasingly focused on management and care, rather than treatment and cure, the voice of the patient becomes discernable again. As Bury (1998) has described, “The contingencies of everyday life reassert themselves and the heterogeneous character of the intersection of the individual’s life worlds become the focus of lay and professional concerns” (p. 25).

Another factor is the expense of providing modern technological healthcare to the ill population. Greater technological care requires more extensive explanation to both patient and insurance provider, thus making way for patient and physician to engage in greater dialogue. Also, as the cost of healthcare rises and coverage shrinks, and as modern medicine continues to focus on cure, rather than therapeutic treatments, increasingly frustrated patients have to turn back to the culture of traditional healing (i.e. alternative and complimentary medicine) as a way to meet their needs. The interest in the other traditions of healing is connected with the expanding growth of Eastern and other traditions of philosophy, spirituality, and healing in the Western world. It is also happening at the same time as what Bury (2001) described as a “recent and powerful democratic impulse leading to a reduction in hierarchical relationships in modern cultures, including those in the medical field” (p. 268).

Technology has also been a factor in re-establishing the patient voice in the illness narrative. The expansion of medical information about illness that is now commonly available to the patient via media coverage and the Internet has resulted in a more equitable footing between doctor and patient. With access to a plethora of information about the origin, course, outcome, and treatment of illness, the doctor’s role as “fount of medical knowledge” and over-arching

expert is weakened. This allows the patient to repossess his or her illness experience and to connect his or her personal experience with many sources of medical narrative. This evolution lays the groundwork for patients to progress from passive compliance to a more active participatory stance, and to reestablish themselves as the primary author of their illness story.

Understanding the Illness Narrative – The Advantages of Pathographical Inquiry

Arthur Kleinman (1989) has suggested, “Illness problems are principal difficulties that symptoms and disabilities create in our life” (p. 4). How we make sense of those symptoms on an individual and social level is the beginning of the illness narrative. Our individual and family biographies create an orientation and explanation towards illness in general. How is illness viewed in our family? Are we allowed to take time to be ill, or do we continue to attempt our daily responsibilities, ignoring symptoms until they interfere with our ability to live? In this way, each person’s illness experience is unique. This uniqueness can form the foundation of a personal narrative that transcends nonfiction literature and provides the reader with a real story of pain, suffering, and survival. John Gunther wrote a pathography about his 17-year-old son, Johnny, who died from a brain tumor. Gunther’s biography of his son’s illness is a testament to how families cope with a diagnosis, a disease, and the ultimate death of a child. After reading his book, I learned how vulnerable we are when a family member is ill. One line in Gunther’s book that shows this vulnerability is when he describes the hospital where his son is being treated. Gunther (1949) passionately stated, “That building! — it became the citadel of all our hopes and fears for more than a year, the prison of all our dreams” (p. 28).

Illness has been described as an interruption of trajectory of one’s life. As part of our conceptualization of self we carry an expectation of our life’s course. Illness interferes with this

expectation in a way that demands an explanation. The crisis of illness and suffering raises two fundamental questions for the sick person and his or her family: “Why me?” and “What can be done?” Arthur Kleinman explains these as the questions of bafflement and control. Kleinman (1989) has declared:

Whereas virtually all healing perspectives across cultures, like religious and moral perspectives, orient sick persons and their circle to the problem of bafflement, the narrow biomedical model eschews this aspect of suffering much as it turns its back on illness (as opposed to disease). (p. 29)

As Bury (2001) described it, the illness narrative is the means by which the connections between the body, self, and society are defined. The illness narrative can provide connections for the ill person by orienting him or her to a place of unity with other ill people. In this place of unity they may share their stories of healing, treatments, cures, experience, and education about a specific disease. For example, Sandra Murray Nettles wrote a pathography, *Crazy Visitation*, on her experience with a noncancerous meningioma brain tumor. She chronicles her journey of misdiagnoses by physicians, memory loss, seizures, and ultimately her recovery. Those with the same diagnosis can find comfort in her words. They can enter a place of empathy, which may be the only place an ill person can find support and solace. Nettles (2001) has stated:

I longed for a veteran voice as I sorted through the symptoms and aftermath of the tumor, but firsthand accounts are rare. I offer my story to those who want a glimpse into the vulnerability created by an unhealthy brain and the restoration of wholeness in the site of secrets and dreams, memory and inhibition, and the origin and ending of all the senses. (p.

5)

Arthur Frank reiterates Nettles' feelings by comparing the illness narrative to a quest story. Frank (1995) has stated, "Quest stories meet suffering head on; they accept illness and seek to *use* it. What is quested for may never be wholly clear, but the quest is defined by the ill person's belief that something is to be gained through the experience" (p. 115). He goes on to say that the ill person is afforded a voice through the quest narrative to tell his or her story. This voice might have been silenced if not for the presence of the illness. A.F. Bingley (2008) has stated, "The telling of one's illness story proves to be an opportunity to find a politicized voice and raise public awareness of issues" (p. 654).

Another advantage of the illness narrative is relational; patients tell stories to explain themselves to others. Teller and listener enter the story space for each other, with the patient's story providing a guide or map that others can follow. The storyteller reclaims his or her suffering, his or her world and relationships, with the creation of the story that can be entered into by the listener. In this way, his or her isolation is reduced and sense of control heightened. Marla Morris (2008) has asserted, "Sickness happens in a web of relations. We do not live in a vacuum. My illness is connected to others' illnesses. I see my condition, then, in relation to others who also suffer" (p. 19). Frank (1995) understood this testimony as an act of "moral action," which created a sense of connection between the individual, the social order of his or her life, and the universe, through the development of a narrative that allows patients to think of themselves as more than just a body, therefore, "disclaiming the vulnerability that all bodies share" (p. 18). Audre Lorde reveals this sentiment in her pathography called *The Cancer Journals*. Her book is about her struggle with breast cancer and what it means to be a woman with only one breast. Lorde helps women fighting breast cancer realize that the definition of a

woman is not determined by the number of breasts she has, but what is found in her heart and soul. Lorde (1997) asserted, “Women have been programmed to view our bodies in terms of how they look and feel to others, rather than how they feel to ourselves, and how we wish to use them” (p. 65-66).

An advantage of pathography for physicians is that it can provide a unique “window” into the experience of their patients, often revealing aspects of patient experience that remain unarticulated in the medical encounter. Pathography can be medically useful for a number of reasons. First, they embody the patient’s point of view on a variety of aspects of a medical experience. Anatole Broyard (1992) wrote his pathography, “When doctors shoved scopes up my urethral canal, I found it helped a lot when they gave me a narrative of what they were doing. Their talking humanized the procedure” (p. 20). Second, the pathography can describe common issues in medical encounters that are often problematic, demonstrating both helpful and harmful ways in which a physician can deliver bad news. Anatole Broyard (1992) has written, “Not every patient can be saved, but his illness may be eased by the way the doctor responds to him (p. 57). Pathographies can also illustrate the patient’s dilemma when confronted with conflicting advice from different medical experts. Audre Lorde wrote about her dilemma with choosing a course of treatment for her cancer. She grappled with what course of action to take to fight her cancer. She contemplates whether to be treated with chemotherapy and radiation, trying experimental therapies, or having a radical mastectomy. She wrote:

I think now what was most important was not what I chose to do so much as that I was conscious of being able to choose, and having chosen, was empowered from having made a decision, done a strike for myself, moved. (1997, p. 32)

Finally, pathographies can provide information about alternative medical treatments from the perspectives of the patients who use such treatments. Le Anne Schreiber wrote a pathography called *Midstream* about her mother's battle and death with pancreatic cancer. Schreiber provided an account when her mother is treated for pain. Schreiber reveals that a medical team decides to use a nerve block—an elaborate and dangerous procedure—to control her mother's pain. The block fails. Her mother was frustrated and desperate so she consulted a Chinese doctor skilled in acupuncture who used a TENS (transcutaneous electrical nerve stimulator) machine. She experienced immediate and dramatic positive results. Schreiber (1990) recalled that the most troubling thing about the whole episode is that the anesthesiologist who performed the nerve block knew about the TENS method for pain relief. The doctor considered it “very effective” and yet never offered it as a therapeutic option (Schreiber, 1990, p. 158). Pathographies can be helpful not only for the people who write them and the patients who read them, but also for physicians who treat the ill.

The Disadvantages of Pathographical Inquiry

Pathography is a personal narrative about a personal event in one's life. According to Bury (1998):

Recent analysts have tended to treat patient narratives as if they represented a form of unalloyed subjective truth, the authentic voice of the patient ‘underdog’ as opposed to the voice of dominant medicine or that produced by a more quantitative survey data. (p. 28)

Illness narratives take many forms, have many uses, and have layers of meaning. This creates a challenging task for the researcher engaged in deconstructing subtle subjective meanings and thematic connections. Thus, narrative analysis is always interpretative and somewhat subjective.

With the amount of medical information available to a patient, he or she must be careful not to self diagnose. Each illness narrative is as unique as the person and disease it describes. The diagnoses and treatments that work for one ill person might not work for another.

Another problem with the illness narrative is that the “distinction between fact and fiction is muddled” (Connelly & Clandinin, 2000, p. 179). Lay people usually write illness narratives. When discussing complicated medical issues a novice might not accurately describe the procedure, medication, or any other aspect of their treatment.

Having described the intricacies of the illness narrative, I now relate it to my inquiry of the HPV vaccine. Everyone has some kind of pathography. It took me months to figure out mine. I had to think hard; I had to search my medical background, my medical biography. I’ve never had a heart attack, a brain tumor, or been on the brink of death; but I do have a story. My pathography is a story that many women share, one that is usually pushed under the carpet and kept silent. I am here to break the silence. Of the four types of pathography, my illness narrative is a testimonial pathography. I wanted to “project a positive attitude towards medicine,” and I was “motivated by didactic or altruistic principles” (Hawkins, 1999a, p. 4).

My story is not only one of illness, but a forum to share with girls, mothers, daughters, partners, whomever will listen about a vaccine that could have prevented my illness if I were afforded the option 20 years ago. Many women will be able to relate to my story; it is not an exclusive experience. For those women, particularly the young, I have presented an inquiry of

information, an inquiry of self-revelation, and an inquiry of empowerment. Through the journey of medicine and cervical cancer, this inquiry presents a very real picture of how women are marginalized in all societies of the world. A picture that details a serious debate in this country about the health of women and a vaccine with both positive and negative implications. After reading this inquiry, one must decide which side of the fence to stand on – the side of political mandates or the side of free choice and autonomy. One might already draw a conclusion, but I must warn the reader that the decision is not an easy one. There are positives and negatives to both sides. It will be a hard choice. My mantra in writing this inquiry and what has sustained and inspired me through the wee hours of the night is, “I am my sister’s keeper.”

My Illness Story

-Each person is as unique and individual in dying as in living.

Larry Churchill

About 5 years ago I got the dreaded phone call from the gynecologist, or actually his nurse. She was quite terse as she told me that she had my results from my annual Pap exam, and pathologists found irregular cells. My heart sank, and I immediately thought I had cervical cancer. I asked her, as my heart raced, “What does this mean? What do I need to do? How did this happen to me? What is this going to do to the chances of me having a baby?” She did not want to hear my litany of questions; her job was just to inform me. She told me to schedule a follow-up appointment with the doctor, and he would explain everything to me. I made the first available appointment possible. It would be 7 days from receiving the news. I had 7 days to fret, to do Internet research, to plan what felt like the rest of my short life, or as Broyard (1992) wrote, “I thought that time had tapped me on the shoulder, that I had been given a real deadline at last” (p. 3). Yes, I look back now and think that I was being overly dramatic. However, at the time my

mother-in-law was battling breast cancer, and my best friend's mom was battling ovarian cancer. How could I not think I would be another victim of the cancer plight? One of my greatest hopes for writing my dissertation is to take my difficult experience and use it to inform girls and women of their medical health options. Robin Sharma (2002), an international author, reflected, "I often wonder why we, as human beings, spend so much of our lives focusing on the negative aspects of our most difficult experiences rather than seeing them for what they truly are: our greatest teachers" (p. 47). Sharing my experience with cervical dysplasia allows the reader to understand my personal journey with illness and to provide validity to my inquiry. My pathography was a personal affair, and I chose to expose myself in a very vulnerable way. I hope the reader will appreciate my honesty and acknowledge that HPV is a very real disease that does not discriminate.

The Doctor's Phone Call

It started out like any annual Pap smear exam – an hour in the waiting room reading year old magazines, a vinyl table covered in what feels like sandpaper, a gown that only covers half of the female body, and a cold speculum (an instrument that if carefully examined looks like a medieval torture device). I find the whole Pap smear procedure, which entails "microscopic scrapings taken from a women's cervix" (Gawande, 2002, p. 44), completely humiliating. Thank goodness it only lasts about 50 seconds. On this particular occasion, when the procedure was over I changed clothes, paid my deductible, and quickly ran to my car in hopes of forgetting the last hour and 50 seconds. A week later I expected to receive the postcard that tells everyone who handles the mail that my annual Pap exam was normal and to call in a year to schedule another appointment. The postcard never came.

I was finishing up a long day of teaching by cleaning my middle school science classroom and straightening the chairs when I heard my cell phone vibrating on my desk. It was a call from my gynecologist's office. I thought to myself that something must be wrong; they never call me. Maybe I did not pay the right amount for my deductible, or my insurance was not going to cover the bill. Never did I think my test results were irregular. I was young, healthy, athletic; I was not promiscuous; I did not smoke, drink, or do drugs. Yes, I am the "poster child" for good clean living, or so I thought. I answered the phone and received the dreadful news about the irregular cervical cells. I first called my husband, an emergency room physician, hoping he would tell me everything was okay, it is common, don't worry, life is good. He did not. He told me I would have to have a colposcopy. "A what?" I asked with trepidation. He started to explain the procedure to me when a fellow colleague walked in my classroom and wanted to discuss the next day's carpool agenda. I told my husband I had to go and that we would talk later. My colleague could tell something was wrong. I told her the news I had just received and how it felt like a death sentence. She did not know what to say. I could see the pity in her face. She could not get out of my room fast enough. Did she think it was casually contagious?

I went home that night and immediately jumped on the Internet to weed through the mounds of medical information available in cyberspace. I had to educate myself about my illness. This was an illness that a few Tylenol was not going to cure. That was the surreal part of this whole experience. Before, popping a few pills could cure all my ailments. Headaches, backaches, and menstrual cramps were the extremes of my health complaints. I was fortunate, until now. Rita Charon (2002) stated, "Illness and its counterpart, health, are by definition time-bound" (p. 61). This was my time, my good health was now confronted by my evil illness and

“...the two [would] suffer together...” (Buber, 2002, p. 7). Which would be victorious? Only time would tell.

After doing some research I learned more than I ever wanted to know about my cervix, a colposcope, and a little germ called human papillomavirus (HPV). I was diagnosed with moderate cervical dysplasia (CIN II). There are various levels describing the severity of cervical dysplasia. Dysplasia is a word that means “abnormal or disordered growth” and therefore can be mild (I), moderate (II), or severe (III). CIN, pronounced “sin” (supposedly not meant to reflect the woman being examined) is short for “cervical intra-epithelial neoplasia,” basically a longer way of saying dysplasia. From my research, I learned that if a Pap smear shows one of these levels of dysplasia of the cervix it is not cancer but rather changes in normal cell growth (pre-cancer) that if left alone might – over months or years – develop into cancer (Moore & de Costa, 2004). The HPV vaccine has been shown to “offer 98-100 % protection in preventing CIN II and CIN III caused by HPV types 16 and 18. This may mean fewer cases of abnormal Pap tests in the future” (Krishnan, 2008, p. 155).

At this point I started to feel a little better, albeit the term pre-cancerous was not much comfort. As Arthur Kleinman (1989) acknowledged, “Cancer is an unsettling reminder of the obdurate grain of unpredictability and uncertainty and injustice in the human condition. Cancer forces us to confront our lack of control over our own or others’ death” (p. 20). As a person always in control, this betrayal in my body was new territory for me. Cancer is caused by the uncontrollable growth of cells. I found it ironic that this was one situation that I could not control. My own body’s cells had taken over, they were making the decisions, and there was nothing my mind, soul, or spirit could do about it. Lesley Sharp (2007) has stated, “Our bodies are typically absent from our consciousness when we are healthy. When the body fails us, we

suddenly become acutely – and painfully aware of its presence and our dependence on it” (p. 8). A healthy body is taken advantage of on a daily basis; one uses it, one abuses it not giving a second thought to its care. When our bodies fail us we realize the importance of health, and we become consumed with making it better. The goal becomes returning to the pre-ill body so that life can return to normal.

The Procedure

Seven days finally passed, and at 10:15 in the morning I was scheduled to meet with my gynecologist to have a colposcopy and cyrotherapy. A colposcopy is a way a gynecologist can examine the vagina, vulva (vagina opening) and cervix closely. A colposcope is an instrument that shines a light on the cervix and magnifies the view for the doctor (Welch, 2004). At the beginning of the exam, I had to lie on the sandpaper table and place my feet in the stirrups as I had for the Pap smear. My doctor inserted a speculum and opened it slightly so he could see my cervix. He then applied a vinegar solution to my cervix with a cotton ball or swab. The vinegar makes abnormal tissue turn white so my doctor could identify areas that might need further evaluation. As all of this was happening, Dr. Peterman was trying to converse with me about trivial matters such as my job and if I had any plans for the winter break. I knew he was only trying to put me at ease, but at this point I had no interest in talking. I was actually counting the number of ceiling tiles in the box of a room I was in with the doctor and nurse. There were roughly 19. How did I remember that? I do not know; maybe mild trauma does strange things to my memory.

When the colposcopy portion of the procedure was over, Dr. Peterman started with the cyrotherapy. Cyrotherapy, or freezing, is done by placing a probe against the cervix, which cools the cervix to sub-zero temperatures. The cells damaged by freezing are shed over the next week

or so. Wherever Dr. Peterman saw a white tint to my cervix he froze it with the probe. He told me that I might experience cramping or a slight uncomfortable feeling during the procedure. I thought, okay, I can handle cramping or slight discomfort. Obviously, Dr. Peterman did not have a cervix nor had he never experienced cryotherapy because slight discomfort is not the appropriate description of what I experienced. I felt like someone was jabbing me with a hot poker. I had to do everything not to scream. Thank goodness the procedure was over within a few seconds. He told me everything went great, and I might experience some cramping the rest of the day. I could take Motrin™ for the pain. I asked him what my prognosis was now that I had had these two procedures. Dr. Peterman told me that he felt confident that he froze all the suspicious areas and that I would need another Pap smear in 6 months.

As I recovered from this procedure, I began to wonder what caused cervical dysplasia? I have always been interested in the science of disease and cure ever since I learned about Edward Jenner, the scientist who discovered the smallpox vaccine. In 1796 he scraped pus from the sore of a dairymaid infected with cowpox into an incision on a healthy boy's arm. This event marked the birth of the smallpox vaccine, and the beginning of vaccinology. In 1806, Thomas Jefferson declared in a letter to Jenner:

You have erased from the calendar of human afflictions one of its greatest. Yours is the comfortable reflection that mankind can never forget that you have lived. Future nations will know by history that the loathsome smallpox has existed. (Baron, 1838, p.2)

The story of Edward Jenner is an important one to me. Even though his risky procedure helped to eradicate smallpox, he was criticized for the lack of ethical judgment in endangering a young, healthy boy. Vaccinators like Jenner who used cowpox experienced both hostility and derision. David Koplow has stated, "Jenner's proposals ... stimulated strong reactions: both profound

celebrations for salvation from smallpox, and intense, sporadic opposition for promoting an allegedly unnatural and dangerous deviation from established medical practice” (2003, p. 54).

From my research and personal experience with cervical dysplasia, I became interested in the national debate that surrounds the HPV vaccine. It is a vaccine that could drastically reduce the number of women who are diagnosed with cervical dysplasia or who die from cervical cancer each year.

Significance of the Study for Curriculum Studies

My dissertation is important for the curriculum studies field because medicine, illness, and science are scarcely represented. In today’s ever advancing technological world, why do we not see more of an emphasis on science, biotechnology, mathematics, and medicine within the curriculum theory literature? Francis Connelly, in the forward of Delese Wear’s book on the Medical Academy, has stated, “Science reigns” (1997, p. ix). But when reviewing the curriculum studies literature, science is scant. Jacob Heller (2008) has asserted, “We simultaneously understand vaccines as a shield against disease, a right of passage for children and parents, and an expression of our science, civilization, modernity, and morality” (p. 1). In describing vaccines this way, curriculum studies is remiss not to include such an important part of our health and well-being into its literature. Marla Morris (2008) has stated, “Medicine is a torture chamber. Medicine is sadism. And yet – without doctors and medicines many of us would be dead. A debt is owed” (p. 65). Despite vaccines widespread use and their predominant role in medicine, health, and in the reduction of infectious diseases, they are under-studied and under-theorized. My inquiry pertaining to the HPV vaccine was an investigation into its nature and origin that helps us understand it as a cultural as opposed to strictly medical or scientific phenomenon.

It is time to find a place for vaccines in the curriculum discourse, and a dialogue of the social construction of the HPV vaccine controversy in our American culture be discussed. Delese Wear and Lois LaCivita Nixon (1994) have written, “The ‘unknown’ where we venture into women’s bodies and medical/health-related experiences can be explored in multiple, conflicting, overlapping, sometimes uncharted spheres of meaning” (p. 2). When discussing the HPV vaccine controversy “multiple spheres” emerge. These spheres make up the framework for my dissertation – the political sphere, the social sphere, and the bioethical sphere. My inquiry deconstructs each of these spheres in order to understand the complexity of the HPV vaccine controversy.

Pinar, Reynolds, Slattery, and Taubman (2004) have opined, “Many curriculum specialists are so caught up in their individual perspectives that they feel little obligation to present the perspectives of others with whom they might disagree. That breakdown in the sense of collective effort is a major problem facing the field today” (p. 5). One of my intentions in writing this work was to embed science, medicine, and illness into the field of curriculum theory. Marla Morris recently wrote a book about teaching and illness. Morris (2008) has contended, “To educate about illness is key. Learning about illness and the course the illness might take are necessary steps along the difficult path of life’s way” (p. 1). In sharing my story of illness I hope to educate women and adolescent girls on one of the most widespread sexually transmitted diseases in the United States. We must begin the “complicated conversation” about sex and disease. Adina Nack (2008) has stated, “A recent study pointed out, ‘while these diseases [HPV and HSV] are of epidemic proportion, we actually see surprising little about them in the media, and we talk about them even less” (p. 3).

My inquiry was the “complicated conversation” that represents the heart and soul of curriculum theory (Pinar, 2000, p. 30). Pinar (2000) has stated, “Curriculum understood as *currere* [is] a form of social psychoanalysis, a complicated conversation with myself and others, the point of which is movement: autobiographic, political, cultural” (p. 30). With a thorough discussion of the HPV vaccine controversy, my story is the autobiographic portion, the government’s mandate is the political portion, and the backlash from parents, religious leaders, and conservatives is the cultural portion.

William Schubert makes a similar point that curriculum is so much more than what is presented in a textbook. Schubert (1986) has asserted, “Curriculum thoughts, decisions, and practices are socially, politically, and culturally constructed. They are powerfully governed by economic and legal contexts in which they exist. Moreover, the values of the day exert profound influence on curriculum” (p. 93). What values are we teaching children in today’s political climate? Are we teaching them to think critically about the world around them? Can we expect an 11- or 12-year-old girl to understand her options when presented with choice of receiving the HPV vaccine? What if the choice becomes a mandate? Will she be able to make a critical decision about her health and well-being? Nel Noddings (2006), stated, “Possibly no goal of education is more important – or more neglected – than self-understanding” (p. 10). Curriculum must be about the whole person, not just reading, writing, and arithmetic. Understanding the mind and body connection will allow students to have a more holistic academic experience.

If we compare the critical gaze of vaccines to the sociological inquiry that curriculum theorists continually discuss, we see a correlation of traditional themes that run deep within the field of curriculum like social class, capitalism, power, gender roles, medical institutions, racial categories, sexual behaviors, and emotions. These themes become evident when the HPV

vaccine controversy is analyzed. Discussing class, gender, and race within the context of vaccines and curriculum studies seems to threaten our comfort level. In order to prepare students to participate intelligently and democratically in a pluralistic society, teachers need to create environments and curricula where students can actively engage with other people to overcome social obstacles (Dewey, 1997). This would happen in environments that allow the individual to inquire, imagine, act, feel, talk, develop a sense of community, think critically about their world, develop his or her own voice, make choices (and suffer their consequence), share ideas, use a wide range of tools and materials, construct knowledge with others, and participate in learning activities that are connected to his or her life.

Pinar, Reynolds, Slattery, & Taubman (2004) have stated that the aim of curriculum studies “is to present a mosaic, even if, at times, it will sound (to change momentarily from a visual to an auditory image) like a cacophony of individuals’ voices so that the beginning student might see this quilt, might hear the complicated symphony, that is the contemporary curriculum field” (p. 5). Discussing science, illness, and medicine in the realm of curriculum studies allowed me to present an important educational issue in a field that is otherwise devoid of such topics. This inquiry added a missing piece of the curriculum studies quilt.

Methodology

My dissertation has educated the reader on the causes of cervical dysplasia, the incidence of cervical cancer, the science behind the first vaccine ever developed to prevent cancer, specifically cervical cancer, and the political and social ramifications of inoculating adolescent girls. My work was grounded in bioethical feminist theory, which included the work of Rosemarie Tong and Susan Sherwin.

Current literature tends to pit parents, social conservatives, and religious leaders against

the government and pharmaceutical companies. By dissecting the political, social, and bioethical controversy that surrounds the HPV vaccine I hope to convey a transparent representation of the benefits of the vaccine, the greed of the pharmaceutical industry, the mandating motives of the politicians, and the legitimate concerns of parents and bioethical feminists.

The roots of my inquiry lie in the fact that I have experienced cervical disease. It is too late for me to receive the vaccine, but through my inquiry I educate other women and girls of the harmful effects of HPV exposure. My form of inquiry was pathography. My pathography is a story that many women share, one that is usually pushed under the carpet and kept silent. I am here to break the silence. I am here to tell my story; and as Anatole Broyard says, this will be my “literary aspirin” (1992, p.18). My story is not only one of illness, but a forum to share with girls, mothers, daughters, partners, or whoever will read about a vaccine that possibly could have prevented my illness. My narrative was a testimonial pathography. I “project a positive attitude towards medicine,” and I was “motivated by didactic or altruistic principles” (Hawkins, 1999a, p. 4).

My research focused on publicly available resources of information such as medical journals, government reports (federal and state), non-governmental organization (NGO) reports, newspapers, and books. I began with a background discussion of HPV, cervical cancer, and vaccines. I then discussed the history, definition, and application of bioethical feminist theory as a theoretical framework. I then examined the controversy surrounding the HPV vaccine. I discussed political, social, and ethical ramifications surrounding the controversy behind the government’s push to mandate the HPV vaccine for school enrollment. In the final section of this dissertation, I focused on the future of vaccine with a discussion of ways to reduce the opposition to vaccine mandates.

Limitations of Study

Because this is a theoretical dissertation, there is no direct data collected from physicians, pharmaceutical representatives, politicians, or parents. All data obtained for this inquiry were retrieved via the Internet, journals, and books.

Definition of Terms

Bioethical Feminist Theory – examines the history and current issues of harm, inequality, and disadvantage based on gender in the healthcare industry.

Vaccine – A substance that introduces a whole or partial version of a pathogenic microorganism into the body in order to train the immune system to defend itself when the organism threatens to cause an infection through natural means” (Allen, A., 2007, p. 14).

Mandate – a government order to do something.

Cervical cancer – Cervical cancer is cancer of the cervix. The cervix is the lower, narrow portion of the uterus.

Human papillomavirus (HPV) – a species- and tissue-specific DNA virus that infects surface cells that cover the skin, mouth, esophagus, upper airways, urethra, anus, vagina, and the cervix (Fiander & Tristram, 2007, Henderson & Yasgur, 2002).

Centers for Disease Control (CDC) – part of the U.S. Department of Health and Human Services. The CDC’s purpose is to protect public health and safety by providing current information, statistics, research data, and educational materials.

Gardasil[®] – the HPV vaccine produced by Merck & Co.

Summary

Although he would recommend that girls receive the HPV vaccine, physician Louis Cooper, a past president of the American Academy of Pediatrics, believes now is not the right

time to push for a mandatory immunization law. The public, he said, is increasingly wary of new vaccines and of medicine in general (cited in Hendricks, 2007). “Public trust is at the heart of all public health measures” noted Cooper; pushing for mandatory HPV vaccination now could further erode that trust (cited in Hendricks, 2007, ¶22). Cooper said there has been a backlash among some groups of parents as the number of required vaccinations has grown. He believes the public has grown increasingly skeptical of new vaccines for all sorts of reasons—medical, religious, political (Hendricks, 2007). So in the current climate, Cooper favors waiting awhile before advocating the proposed laws, to afford the public the time to learn about the vaccine and to give health professionals a chance to gather more data on the vaccine’s risks and benefits, which could build a compelling case for mandatory vaccination. For now, Cooper advocates parents to be the ones to decide whether their daughters get vaccinated.

Before government officials decide whether the HPV vaccine should be mandated, ethical concerns must be alleviated. There are three complementary steps that can help calm parental fears and promote the purpose of this vaccine: which is to save the lives of women. First, the public must realize that the HPV vaccine has the potential for decreasing the number of women who contract cervical cancer. Second, public health officials need to stress that the reason it must be given early in life is that inoculation at that point provides that best chance of lifetime protection. Last and most important, there must be a complete separation of the medical matter of preventing cancer from the moral matter regarding premarital sex. Health officials must make serious attempts to reach out to the religious community, which has moral qualms. Perhaps Merck can circumvent this controversy. While promoting the inclusion of Gardasil® as a standard or required form of vaccination, the company might also work with family-focused groups who oppose sex outside of marriage to co-develop educational tools for discouraging premature

sexual relationships citing medical, emotional, and practical reasons for doing so. If these three issues are addressed, the government will not have to mandate Gardasil[®], because parents will understand that they are protecting their daughters against the second leading cause of cancer death in women (Krishnan, 2008).

My dissertation embedded the vaccine controversy within the curriculum studies field. Curriculum studies involves the political, social, cultural, and religious issues of the schooling process. The same can be said about vaccines and their place in society. The ironic twist is that before a student can even encounter the curriculum process, he or she must be vaccinated.

CHAPTER 2

THEORETICAL FRAMEWORK

My approach to researching the HPV vaccine controversy is framed around bioethical feminist theory. This chapter provides a complete exploration of bioethical feminist theory. The next few sections of this chapter provide a breakdown of bioethical feminist theory into its different perspectives. I have begun by providing a brief overview of bioethics as a field of study followed by a summation of the field of feminist theory.

The Bioethical Perspective – An Overview of Bioethics

The bioethics movement was triggered by protest against gross abuses of medical authority such as Nazi doctors' experiments on nonconsenting concentration camp inmates and the Tuskegee Syphilis Study, a 40-year "experiment" on poor black men who were misled into believing they were receiving medical treatment. At the beginning of this millennium advancements in genetic and reproductive technologies presented society with many new ethical dilemmas. Should we be allowed to select the sex of a child? Should we clone embryos for spare parts? Does an embryo have rights? Should we allow DNA fingerprinting of all citizens? Should a terminally ill patient have the right to take his or her own life with the help of assisted suicide? These dilemmas have led to a field called "bioethics." Mary Mahowald (2006) has asserted, "The majority of questions addressed in contemporary bioethics involve the beginning and end of life" (p. 50).

The word bioethics literally means the ethics of life. We have understood that ethics is the branch of philosophy concerned with how we should decide what is morally wrong and what is morally right (Reiss, 2002). Sometimes the words "ethics" and "morals" are used interchangeably. We all have to make moral decisions daily on matters great or more often small

about what is the right thing to do: Should I have an abortion? Should I obey the law and drive the speed limit? Should I lie to get out of an uncomfortable situation? We may give much thought, little thought, or practically no thought at all to such questions. Ethics, though, is a specific discipline that tries to probe the reasoning behind a moral life, particularly by critically analyzing the thinking, which is or could be used to justify our moral choices and actions in particular situations. Bioethics is a field that tries to answer the moral decisions involving life and death such as choices about dying, reproduction, genetics, disability, and disease. Susan Wolf (1997) has defined bioethics as, “The study and formulation of the ethics of health care and the biological sciences. I do not dwell on the distinction between ethics and morals; bioethics usually is used to encompass both” (p. 7).

Modern bioethics is a collaboration of several disciplines, with their relative importance shifting over time. Philosophers, lawyers, physicians, and scientists have played major roles from the beginning. Theologians were significant players early, but more recently have worried about a loss of influence (McCormick, 1989). Meanwhile, nurses, medical sociologists, and anthropologists have begun to play a larger role in the bioethical field.

Modern bioethics began in the late 1960s and early 1970s. It has focused on the passionate plea for patients’ and research subjects’ moral and legal rights. It grew up alongside other rights movements such as the civil and women’s rights movements. Bioethics has concerned itself with the protection of vulnerable patients and research subjects, the relationship between medical and scientific fact and social meaning, and the ethics that should guide physicians and scientists (Wolf, 1997).

Bioethics in Relation to Other Academic Fields

Bioethics has been scantily represented in other major academic developments like

feminism, critical race theory, and postmodernism. One might conclude that bioethics has managed a sort of isolation from major trends in the academic field. Wolf (1997) has argued that bioethics is more selective than isolating saying, “The upsurge of academic interest in narrative and narrative ethics has spawned attention to narrative and narrative ethics in bioethics” (p. 20). The appeal for narrative ethics is probably based on the traditional importance of cases in medicine and the scientific study of human beings. Cases, after all, are mini-narratives. Bioethicists intrigued with narrative and narrative ethics have called for richer and more complete case narratives. Dena Davis (1991) has asserted, “When cases are described thinly to protect patient confidentiality, they teach us only what we put into them. Thick description, like myth, allows a fuller moral response” (p. 12). Thus the enthusiasm for narrative among bioethicists meshes nicely with a long tradition in medicine and science. Mary Mahowald (2006) has stated, “The contribution of narrative theory [to ethics] is mainly epistemological because it stresses the need for attention to different ‘stories’ told by different authors from different standpoints about specific cases. Attention to these stories is crucial to the knowledge base required for ethical decision-making” (p. 11). The idea of narrative being an important aspect of bioethical theory complements my form of inquiry, which is illness narrative. Illness narrative is a form of inquiry in which a person shares his or her story of illness.

Critical race theory and postmodernism have no obvious correlation to the practices of medicine and science (Wolf, 1997). There is an association though. Analysis of the role of race in medicine can teach us a great deal. In the United States, health disparities have been framed by categories of race. Racial health disparities have been documented for cervical cancer, cardiovascular disease, cancer, diabetes, HIV/AIDS, and numerous other diseases and measures of health status. Although such disparities can be read as symptoms of disparities in healthcare

access, pervasive social and economic inequities, and discrimination, some have suggested that the disparities might be due, at least in part, to biological differences based on race (Yu, Goering, & Fullerton, 2009).

In the case of postmodernism, Michel Foucault's early *Birth of the Clinic* could have forged the way for a rich deconstructive and postmodern look at medical and scientific practices and texts. Foucault's idea of the "Gaze" reiterates the importance of ethical narrative in medicine. The "Gaze" was a term used by Foucault to denote the dehumanizing medical separation of the patient's body from the patient's person. He stresses the need for a reconnection in the patient-physician relationship. Foucault (1973) has written, "There is boundary, form, and meaning only if interrogation and examination are connected with each other, defining at the level of fundamental structures the meeting place of doctor and patient" (p. 111). Foucault's idea of "interrogation and examination" makes a strong argument for case narrative within the medical field and bioethics.

Bioethics and Politics

The field of bioethics speaks to a broad range of human inquiry, ranging from debates over the boundaries of life, the allocation of healthcare resources, and the right to turn down medical care for religious or cultural reasons. There is a debate among bioethicists about the precise limits of their discipline. Should the field of bioethics concern itself with the ethical evaluation of all questions involving medicine, human research, and biology? Some bioethicists would narrow ethical evaluation to medical treatments and technological advancements pertaining to only humans. Others might broaden their scope to cover any organism capable of feeling fear and pain.

In recent years bioethics has gone from the philosophical lens to the political lens. Take

any number of recent examples – from the right-to-die Terri Schiavo case, to human embryonic stem cell research, to, most recently, the California women implanted with six embryos and then giving birth to octuplets – that place bioethics squarely in the middle of the Culture Wars. These few examples have sparked public interest and emotion. It seems everyone has an opinion about the ethics of some of the recent medical and scientific stories that have flooded the media. There seems to be a liberal stance and a conservative stance when it comes to issues like euthanasia, abortion, stem cell research, and reproductive technologies, leaving out the important bioethical stance. The mingling of bioethics and politics is here to stay, and bioethicists can and ought to play a role in pressing societal issues. Bioethics as scholarship should be able to coexist with bioethics as politics without being subsumed under it (Kahn, 2006). One way to assure this outcome is to treat the two as distinct areas much as political science is distinct from political consulting. A healthy bioethics should expect and welcome struggles between opposing viewpoints. The issues are difficult, contentious, and complex; disagreements are bound to occur. Bioethics as a field should see a lively exposure of those disagreements. But they should take place *within* bioethics, not the political arena.

The Epistemology of Bioethics

According to Susan Wolf (1996), it is not clear whether bioethics has an explicit epistemology, a theory of how bioethical knowledge is produced. One widely held, although not universal, notion within bioethics is that generating bioethical insight does not require agreement at the level of fundamental theory. Wolf (1996) has stated, “[Bioethicists] reject the notion that one must choose a single theory from among the competitors” (p. 24). Bioethicists tend to draw on the societal norms and principles to assess a particular situation or issue. Beauchamp and Childress (2001) have asserted, “Far more social consensus exists about principles and rules

drawn from the common morality... than about theories” (p. 102). If the generation of bioethics knowledge begins with “common morality” or is usually approached as a matter of achieving reasoned agreement, the relevant community and rules of agreement are rarely stated. Having provided an overview of bioethics, I will now turn to the feminist aspect of my theoretical framework.

The Feminist Perspective – An Overview of Feminist Theory

It seems that the majority of current bioethical issues reported in the media have to do with the woman and her body. For example, the California woman who gave birth to octuplets has generated a firestorm of controversy involving the ethics of assisted reproduction. Another example, especially popular in last year’s presidential election, is a woman’s right to have an abortion. Abortion is an issue that deeply divides American society. Generally, the bioethical argument centers between the right-to-life and the pro-choice ideologies. Against this background, it becomes truly perplexing why modern bioethics has paid so little attention to gender and feminist work.

The term "feminism" may bring to mind stereotypical images of Gloria Steinem, Betty Friedan, and the "bra-burners" of the 1970s marching through the streets with signs reading “Equal Pay for Equal Work,” “No More Miss America,” “The Personal Is Political,” and “Pass the ERA (Equal Rights Amendment).” Whereas these images do convey some of the key events and leaders of the so-called second wave of feminism in the United States, they do not do justice to the complexities of the feminist social movement. Although the activism of the 1970s has tempered, feminism, as an academic focus, has thrived throughout the 1980s and 1990s and continues to thrive today. A primary task of feminist scholarship has been clarifying the meaning of feminism and how it can influence research in the humanities and social sciences. The

clarification of feminism is “a central problem within feminist discourse” (hooks, 2000, p. 18). bell hooks has argued that feminists cannot “arrive at a consensus of opinion about what feminism is or accept definition(s) that could serve as points of unification” (2000, p. 18). The idea that feminism represents a fight for social, economic, and political equality with men is distressing to hooks. She has stated, “Since men are not equal in white supremacist, capitalist, patriarchal class structure, which men do women want to be equal to?” (hooks, 2000, p. 19). Defining feminism in terms of equality is a difficult task for the very reason hooks contends. Susan Sherwin has defined feminism in terms of oppression instead of inequality. Sherwin (1992), in a consistent and more epistemological manner, defines feminism as “the name given to various theories that help reveal the multiple, gender-specific patterns of harm that constitute women’s oppression. It is also the term used to characterize the complex, diverse political movement to eliminate all such forms of oppression” (p. 1). When a woman is oppressed she is held back from reaching her full potential due to social, cultural, political, or economic injustices. The primary goal of the feminist movement is to end sexist oppression in all its forms. hooks (2000) has stated, “Its [feminism] aim is not to benefit solely any specific group of women, any particular race or class of women. It does not privilege women over men” (p. 28).

Feminism has also been defined as the political movement to end women’s subordination (Jaggar, 1989). Feminist work takes gender and sex as centrally important analytic categories, seeks to understand their operation in the world, and strives to change the distribution and use of power to stop the oppression of women (Wolf, 1996).

From my research, I have found that no one theory or perspective constitutes “feminism”; there are a number of feminisms, which some feminist writers have classified. Rosemarie Tong (2009) has stated, “Feminist thought is old enough to have a history complete with a set of

labels: liberal, radical, Marxist/socialist, psychoanalytic, care-focused, multicultural/global/colonial, ecofeminist, and postmodern/third wave” (p. 1). Nonetheless, feminist inquiry provides a wide range of perspectives on social, cultural, and political phenomena.

Common Themes within Feminism

The assemblage of scholars who consider themselves feminists is large and diverse, representing a broad range of different opinions and perspectives (Pellegrino, 1993). Despite this array of views, it is possible to identify some common themes. First, feminists have shared the recognition that women are oppressed in society and an understanding that their oppression takes many different forms, compounded often by other forms of oppression based on characteristics such as race, ethnicity, sexual orientation, and economic class. Susan Sherwin (1992) has stated, “Because feminists believe that oppression is objectionable on both moral and political grounds, most are committed to transforming society in ways that will ensure the elimination of oppression in all its forms” (p. 47). Second, much of the harm of sexism has been obvious and thus can be readily challenged. For example, women are disproportionately subjected to domestic violence and sexual assault, which can result in a sense of insecurity and vulnerability in them. Third, women are subjected to economic disadvantage in the work place. Women earn considerably less than men in the same position. Fourth, the predominance of men, especially White, middle-class men, in positions of influence in virtually all segments of society (legal, political, financial, cultural, medical, and military) is dominant. Susan Sherwin (1992) has pointed out, “Feminists have shown that male standards have been consistently taken as the norm from which theories are developed and against which they are tested; this has left women in the position of being either ignored altogether or treated as deviant” (p. 1). Finally, the implicit male

bias in our language is subtle, but also creates a form of sexism. The tendency to confuse gender-specific male forms of expression with supposedly neutral generic forms of expression perpetuates culturally embedded notion of male-defined norms and assumptions of female deviance (Sherwin, 1992). For example, words like *chairman*, *manpower*, and *mankind* exude a strong male bias and undermine the influence of women in society. These examples illustrate major themes that feminists strive to eradicate within the various institutions that shape society.

The Epistemology of Feminism

Just as there is no single feminist perspective or theory, there is no single feminist epistemology. In general, feminist epistemologies investigate the relationship of power, gender, and the means of generating authoritative knowledge. Their general goal is “the expansion of democracy in the production of knowledge” (Tong, 2009, p. 217). Feminism has identified ways in which dominant conceptions and practices of knowledge attribution, acquisitions, and justification systematically disadvantage women and other subordinate groups, and has strived to reform these conceptions and practices so that they serve the interests of these oppressed groups. Dominant knowledge practices disadvantage women by excluding them from inquiry, denying them epistemic authority, and producing theories of women that represent them as inferior, deviant, or significant only in the ways they serve male interests. Feminist epistemologists trace these failures to flawed conceptions of knowledge, knowers, objectivity, and scientific methodology.

There are three main feminist epistemologies that have become popular over the last quarter-century. They are rational-empirical epistemology, standpoint epistemology, and postmodern anti-epistemology. Rational-empirical epistemology is the view that experience provides the sole, or at least the primary, justification for all knowledge. Feminist empiricists are

concerned with the impact on inquiry of social practices relating to gender, race, class, and other bases of inequality.

Standpoint theories claim to represent the world from a particular socially situated perspective that can lay a claim to epistemic privilege or authority. The defining characteristic of the standpoint feminist approach is to “give voice” to oppressed people in social situations (Bui, 2007). The idea of giving a voice to the less powerful members of the social order stems from the belief that they encounter a different reality as a result of their societal oppression. Sandra Harding has pointed out, “Whatever the kind of difference identified, the point ... is that women’s [or any oppressed person’s] ‘difference’ is only difference, not a sign of inferiority” (1991, p. 122). Feminist standpoint theory has begun with the idea that the standpoint or position in society of women provides a vantage point from which to view women’s social reality (Swigonski, 1994). Nancy Hartsock, in her classic study of feminist standpoint epistemology, argued that women’s intuition provides a standpoint from which she can envision possibilities for overcoming oppression and building a better society. It was Hartsock’s belief that such a vision is superior to a masculine focus on hierarchy, dominance, and oppositional thinking. Ways of knowing informed by motive of caring for everyone’s needs will produce more valuable representations than ways of knowing informed by the interests of domination. A feminist standpoint allows us to “go beneath” patriarchal structures and understand them as “perverse inversions of more humane social relations” (Hartsock, 1998, p. 107).

Postmodern anti-epistemology dictates no “true” facts exist for anyone to discover, regardless of their standpoint. Rosemarie Tong (1997) has stated, “Postmodern feminists rebuke feminists who formulate general theories about women’s subordinate status in society” (p. 89).

All three approaches to feminist epistemology embrace pluralism and reject totalizing

theories. No matter how the knowledge is formed, feminism is a philosophy that “urges us to revise the values, perceptions, and concerns that shape how we look at human interactions, so that we may take account of the place of those interactions in the broader set of human relationships” (Sherwin, 1992, p. 5).

The Melding of Bioethics and Feminism: An Overview of the History and the Strengths of Bioethical Feminist Theory

Up to this point in my dissertation I have provided a synopsis of bioethics and feminism. This section will provide an overview of bioethical feminist theory. I discuss the role of bioethical feminist theory as the theoretical framework for my dissertation.

What might a bioethics attentive to gender and feminist analysis look like? Bioethical feminist theory recognizes that moral and ethical analysis requires attention to gender. There is a long history of harm, inequality, and disadvantage based on gender in the healthcare industry that has been ignored completely, which is ironic because according to Barbara Ehrenreich and Deirdre English (1973), “Women have always been healers” (p. 3). Wolf (1996) asserts, “Ignoring it merely helps to keep such oppression invisible and alive” (p. 21). A principal characteristic of bioethical feminist theory is the critical interest it takes in oppressive aspects of medical organization and practice.

Bioethical feminist theory began to emerge as a new area of academic interest when feminist scholars turned their attention to the field of bioethics and the field of medicine and science. Both bioethics and “Second Wave” feminism gathered momentum in the 1960s, a pivotal era for social turmoil. Sandra Harding (1991) has written:

It is at this moment that feminism and other liberatory social movements appear on the scene with agendas that include generating new science. Women need sciences and

technologies that are for women and that are *for* women in *every class, race, and culture*.
(p. 5)

In this second wave, feminists pushed beyond the early quest for political rights to the fight for greater equality in education, the workplace, and at home.

The long history of women's interest in health care issues extends prior to the seizure of practices of midwifery and nursing by the medical profession. Ehrenreich and English (1973) have asserted, "The women's health movement of today has ancient roots in the medieval covens, and its opponents have as their ancestors those who ruthlessly forced the elimination of witches" (p. 6). It was those historic influences that fed into protest movements of the 1960s resurgence of feminism. That revival reinvigorated and extended longstanding concerns and directed attention to areas of health care where women's interests were neglected, such as access to birth control, abortion, pregnancy, and representations of female sexuality (Wolf, 1996). The vigilance of the women's movement in the 1960s and early 1970s called attention to sexist biases in medical research and practice. Susan Wolf (1996) has stated:

Our societal definitions of what constitutes illness and thus merits medical attention have been influenced by gender. Historians have argued those defining women's psychological reactions as madness and women's usual physical functioning as pathological have reflected the biases and misogyny of the day. (p. 12)

Protest against the widespread exclusion of women from clinical trials, particularly in the United States, swelled momentum even further. Feminists campaigned for increased breast cancer research, more convenient and cheaper contraceptive methods, research on the physiology of menopause, and elimination of unnecessary surgical interventions, particularly hysterectomies, Caesarean sections, and radical mastectomies (Tong, 1997). Advocacy groups have struggled to

raise public awareness of women's health issues, influence health policy, and act as a counterforce to organized medicine and the pharmaceutical industry.

Feminist scholars began to complement the agenda of health care activists. They documented the erosion of abortion access following the 1973 *Roe v. Wade* Supreme Court decision, and critiqued childbirth practices that sacrifice the interests of the birthing woman to the convenience of her obstetrician. By the 1980s, feminist bioethics scholarship was being widely circulated in feminist publications, and a small portion of this effort was surfacing in bioethics journals. Unfortunately, most of the feminist literature published was often mistakenly assumed to address "women's concerns" – also known as a special ethics for women. Feminist contributions to texts were included, but they were confined to topics relating to reproductive issues.

One of the turning points in feminist bioethics was the publishing of Susan Sherwin's book called *No Longer Patient: Feminist Ethics and Health Care* (1992). This was the first full-length book dedicated to bioethical feminist theory. In this groundbreaking work, Sherwin expanded feminist bioethics in a new direction that circumvented the prevalent theoretical approaches of the dominant bioethics framework and demonstrated its shortcomings. Sherwin (1992) has asserted, "Feminism expands the scope of bioethics, for it proposes that additional considerations be raised in the ethical evaluation of specific practices: it demands that we consider the role of each action or practice with respect to the general structures of oppression in society" (p. 4-5).

The field of medicine and medical research can at times be mechanizing and dehumanizing, especially towards women. There is an underlying power of those in the patriarchal medical authority to define illness (Sherwin, 1992). Women have been especially

harmful by this power. It has evolved into the bizarre conclusion that women are never quite healthy: premenstrual or not premenstrual; hysterical or not hysterical; pregnant or not pregnant; menstruating or not menstruating; menopausal or not menopausal. Susan Sherwin (1992) has asserted, "The decision to view as diseases such elements of women's lives as menstruation, pregnancy, menopause, body size, and feminine behavior forms an integral part of women's general oppression" (p. 179). Bioethical feminists are understandably critical of the indiscriminate classification of common female experience as illness.

The concept of the either/or dichotomy can be extended to HPV vaccine argument. A parent that decides to vaccinate his or her daughter against an STD may be ridiculed for condoning adolescent sex; and a parent who decides not to vaccinate his or her daughter may be ridiculed for not protecting her against an STD that has the potential of causing cancer. Both sides are polarized for doing something wrong. Will there ever be a right answer when it comes to vaccinating adolescent girls against an STD?

More recent bioethical feminist work has sought to bring increased attention to obstacles surrounding policy reforms that could alleviate burdens imposed predominantly on women. Both Jennifer Park's *No Place Like Home: Feminist Ethics and Home Health Care* (2003) and Rosalind Ladd's anthology, *Ethical Issues in Home Health Care* (2002) address the growing problem of caring for the elderly, homebound, and those who risk their own economic security to care for them. They both discuss topics relating to care and justice. Several other bioethical feminists have joined the growing discourse with disability scholars who adapt features of care ethics with issues of justice. One feminist who has argued persuasively for a necessary connection between care and justice is Marilyn Friedman. According to Friedman, the care/justice dichotomy overlap, and if care is morally adequate it involves justice in personal as

well as professional relationships (Friedman, 1987). Similarly, if justice means giving people their due (treating people appropriately), it demands determination of what constitutes due care for each. The application of this concept to health care is obvious: the health practitioner must recognize and respond to the different health needs of each patient (Friedman, 1987).

Two other feminists who have developed discourse in care ethics are Carol Gilligan and Nel Noddings. Both derive their understanding of care from an analysis of women's experience. Gilligan (1982) has stated, "The ideal of care is thus an activity of relationship, of seeing and responding to need, taking care of the world by sustaining the web of connection so that no one is left alone" (p. 62). The idea that care is responding to one's needs is the backbone of bioethical theory. Building relationships of trust also goes along with care and bioethics. The physician-patient relationship must be one of trust in order for treatment to be successful. If the patient does not feel that the physician cares about him or her and there is not a relationship of trust then the healing process will suffer.

Rosemarie Tong (1997) has made a forceful case for incorporating features of a care ethic into bioethical theory to challenge the structures and systems that perpetuate women's disempowerment. She notes that justice and care are closely intertwined on a practical level. Though far greater prestige attaches to high-tech medicine than the mundane tasks of providing quality care to the sick, caring values count heavily in providing high caliber healthcare. Tong (1996) has stated, "Caring can and has served as a trap for women – as a "virtue" that turns women into masochists, living only to serve other people's interests (particularly, men's and children's) while steadfastly neglecting or ignoring their own" (p. 72). Virginia Warren (1992) made a good point that caring tasks of medicine have been stigmatized as "housekeeping tasks" that garner little interest and even less remuneration while "crisis issues" dominate attention and

reward their practitioners handsomely (p. 32). This inequality in the healthcare system is of special concern for bioethical feminists. The majority of health caregivers are women, but they occupy primarily low status, low paying positions. As a result, women's voices are rarely heard in debates over the public and institutional health care policies and practices that shape our medical experiences (Dresser, 1996). In my opinion, nurses, the majority being women who care for the sick, are given very little appreciation. Doctors, the majority being men who care for the sick, are revered as Gods (Warren, 1992). Often when one reads illness narratives, the doctor is thanked for saving the patient's life, and there is no mention of the "Other" people in the healing process. The Other in the medical field is often a woman whose caring, trusting, sympathetic, and compassionate nature contributed to the healing process just as much as the doctor that ordered the medicine (Warren, 1992). Sherwin (1992) has stated, "Speaking with the authority of a discipline devoted to improving the human condition, medical practitioners have been granted the status of the new priesthood within secularized Western culture" (p. 5).

The greatest strength of bioethical feminist theory as a framework is the vast array of discourse among its scholars. There are differing perspectives among bioethical feminists depending on the particular topic of interest. Each bioethical feminist must be sensitive to the possibility that her perspective is offensive or hurtful to others. For example, my view that abortion should only be used in cases of rape, incest, or harm to the mother's life distresses many pro-life women. The fact that I have to be sensitive to other, differing perspectives on abortion does not mean I have to abandon my own perspective. Katharine Bartlett (1990) has made a similar point:

Although I must consider other points of view from the positional stance, I need not accept their truths as my own. Positionality is not a strategy of process and compromise

that seeks to reconcile all competing interests. Rather, it imposes a twin obligation to make commitments based on the current truths and values that have emerged from methods of feminism, and to be open to previously unseen perspectives that might come to alter these commitments. Positionality, however, sets an ideal of self-critical commitment whereby I act, but consider the truths upon which I act subject to further refinement, amendment, and correction. (p. 389)

Rosemarie Tong believes that bioethical feminists need to “develop a feminist methodology in ways that may increase their ability to forge mutually agreeable public policies that actually reduce gender oppression in the world of biomedicine” (1997, p. 96). Bioethical feminist theory can empower women to achieve consensus on issues that have divided them in the past. The eclectic mix of perspectives within bioethical feminist theory can be used to recommend proactive policies that will permit the widest variety as well as the greatest number of women to control their “interconnected reproductive and genetic destinies” (Tong, 1997, p. 98).

Bioethical Feminist Theory as a Theoretical Framework

As the medical field continues to grow and technological advancement pushes the boundaries of the ethical and the unethical, bioethical feminist theory will have its place in scholarly discourse. My intention was to help bioethical feminist theory find its place in curriculum studies.

Bioethical feminist theory is committed to developing analyses that can offer meaningful guidance in the morally troubling situations of real life. Bioethical feminist theory will provide a solid framework for my discussion as I lay out the conflict-ridden story that surrounds the HPV vaccine.

There are several bioethical feminist issues pertaining to this particular vaccine. The vaccine is wrapped in controversy that pits the government and pharmaceutical companies against religious leaders and parents of adolescence girls. It is a fight between the validity of science and the moral and religious views of a society. The HPV vaccine has put a wedge between the ethicality of medicine and the morality of society.

Proponents of the vaccine claim that it will provide unequivocal safeguards against a sexually transmitted virus that causes cervical cancer, but the vaccine has to be administered to girls between the ages of 11 and 12. The Centers for Disease Control and Prevention (CDC) picked this age range because the vaccine has to be given before a girl becomes sexually active. The decision whether to inoculate girls this young poses a moral dilemma to parents, religious leaders, and even some medical professionals. They find themselves asking the following question, “Should preteen girls be vaccinated against a potentially cancer-causing sexually transmitted disease, or will the benefits of vaccinating our girls be outweighed by increased promiscuity and risky sexual behavior?” Although these perceived risks of the vaccine may seem completely unfounded by the scientific community, many parents wonder whether the vaccine is just a “quick fix” to address the consequences of behavioral choices.

In spite of the widespread opposition to the vaccine from parents and religious leaders, many states such as Texas proposed legislation mandating the vaccine be administered to all preteen girls attending public school. Under current proposals, mandates would force adolescent girls to undergo drug therapy (vaccination), when they have no disease, under the presumption that they might get a disease based on future behavior. One might argue that we do have, as public policy, mandatory vaccinations for some infectious diseases like mumps, measles, and rubella (MMR). The difference is that MMR are contagious diseases that can be caught by sitting

next to an infected person in a classroom. HPV is not spread by casual contact. James Colgrove, a professor of sociomedical sciences in the Center for the History and Ethics of Public Health at Columbia University's Mailman School of Public Health, has stated "In general, you use coercion in public health to prevent imminent harm to others. It's the classic jurisdiction in the USA. You don't pass a law requiring something unless it causes imminent harm" (cited in Udesky, 2007, p. 980). Physician Jon Abramson, the chairman of the Advisory Committee on Immunization Practices of the CDC, has explained that protecting children against a virus that is spread by sexual activity is different from preventing the spread of measles (cited in O'Beirne, 2007). Abramson believes that mandating the HPV vaccine "is a much harder case to make, because you're not going to spread it in school unless you are doing something you're not supposed to be doing in school" (cited in O'Beirne, 2007, p. 20). Non-vaccinated students would pose no risk to others while in school. So, does the government have a right to mandate the HPV vaccine? Susan Sherwin (1992) has asserted, "That the trend in medical ethics has been to examine moral issues in context and to avoid dependence on general, abstract rules and rights. The theme of seeking a practical, context-specific approach to ethics is widely stressed" (p. 79). In this case, examining the moral and ethical issue of mandating the HPV vaccine is easy. Bioethical feminist theory would support the parents and religious leaders. One has to wonder why the government would mandate a vaccine for an illness that is not caught by airborne or casual contact. Further investigation into the state of Texas revealed that the governor had financial and political ties to the pharmaceutical company that produces the HPV vaccine.

Currently, the vaccine is gender-specific, recommended for girls only. The American Academy of Pediatrics does not support a school-linked mandate because "there are people who are concerned about gender discrimination because it's a policy that would keep girls out of

school and not boys, because it's a vaccine for girls" (Udesky, 2007, p, 980). From the bioethical feminist theory standpoint, research on vaccinating boys must be further investigated. In the majority of cases, HPV is spread to women through sexual contact with men. Therefore, an understanding of HPV infections in men is critical in reducing the risk of transmission to women.

The Global Perspective of HPV – A Lack of Screening

In the U.S., nearly 3,700 women who will die of cervical cancer will have something in common – no screening (Pap smear) or no treatment follow-up after screening. These facts speak to access to healthcare, and the conclusion is clear – cervical cancer is a disease of disparity (Outterson, 2009). While this technology is widely available and has reduced cervical cancer incidence in industrialized nations, it is not readily available in third world nations in which cervical cancer incidence and mortality is high (Brinkman, Caffrey, Muderspach, Roman, & Kast, 2005). In many developing countries it is the leading cause of cancer death among women (Siddiqui & Perry, 2006). Cervical screening has reduced the incidence of cervical cancer deaths by 70% over the last 50 years. In the U.S., approximately 60 million women receive a Pap smear each year, which results in the diagnosis of 1.25 million women with pre-cancers (Siddiqui & Perry, 2006). However, Nicoletti & Tonelli (2006) have stated, "On average, there are about 9,710 new cases of cervical cancer in the United States each year and 3,700 deaths are attributed to it" (p. 423). The lethality of cervical cancer is even greater worldwide, causing over 470,000 new cases each year and 233,000 deaths (Nicoletti & Tonelli, 2005). The discrepancy is largely due to the decreased availability of affordable screening and treatment in many countries. According to Franco and Harper (2005), Eastern and Southern Africa have the highest incidence and mortality from HPV in the world.

Few countries have the resources and infrastructure necessary to run organized screening

programs, so the poorest regions of the world bear the brunt of the disease. Most women in low-income countries do not have access to routine screening: only 5% have undergone a Pap smear in the past 5 years (Katz & Wright, 2006). In parts of Latin America and the Caribbean, more women die from cervical cancer than from complications of childbirth (Population Reference Bureau, 2006).

Currently, the HPV vaccine is extremely expensive compared to the other mandated vaccines. Bioethically speaking, this in itself produces the marginalization of women in terms of healthcare. If minority women and women living in developing countries are not receiving the proper screening for cervical cancer, then the vaccine would be a great treatment to protect them. Unfortunately, at a cost of \$320 for the complete treatment with the HPV vaccine not all women have financial access to it. The marginalization of women's needs in biomedicine and research continues to be one of the greatest struggles in the field of bioethical feminism. The last section of this chapter outlines the criticisms that are waged against bioethical feminist theory.

Criticisms of Bioethical Feminist Theory

Throughout its short historical span, bioethical feminist theory has been marked by criticism regarding its conceptual framework, methodology, multidisciplinary composition and dynamics, agenda of gender moral issues, and relationships with social institutions and culture of American society. The conceptual framework of bioethical feminist theory is based on societal norms and moral teachings of one's religion. So, bioethical feminist theory has been criticized for not being properly theoretical.

Critics believe feminists' concerns lack mooring in a bona fide ethical theory (Tong, 1996). Feminists themselves hotly contest ideas such as Carol Gilligan's or Nel Noddings' ethics of care. Some object to what they see as its valorization of negative traits born of subordination

and the need to please. A further complaint is that the ethics of care offers too little analytic rigor in facing moral problems. Carol Gilligan's response to such a criticism might have been, "To admit the truth of the women's perspective to the conception of moral development is to recognize for both sexes the importance throughout life of the connection between self and other, the universality of the need for compassion and care" (1982, p. 98).

In contrast, other critics fault feminist approaches to bioethics for being too theoretical; that is, for clinging to the category of gender as the ultimate reference point or foundation for women's diverse experiences, as if gender always mattered to each woman more than her own race or class, for example (Nicholson, 1990). Feminist bioethicists might have responded that so long as gender inequities remain, there will be a need for feminist approaches to bioethics that emphasize women's ways of perceiving, thinking, and acting.

Bioethical feminist theory has also been criticized for being biased and highly personal. Rosemarie Tong (2007) has stated:

An unfortunate, but common effect of realizing that ethical theories are plural rather than singular in number is the feeling that, when all is said and done, ethics is a very relative and highly subjective practice in all realms of human activity. (p. 6)

When bioethical feminists try to invoke major moral theories, most find it difficult to fit the theories' criteria to the problems before them, a restriction that clearly limits their practical usefulness (Tong, 2000). Moreover, many find that a single comprehensive moral theory is inadequate to capture all of their moral intuitions; in such cases they may sometimes find themselves tempted by the attractions of alternative theoretical approaches for addressing different sorts of issues. It has even been argued that there are "no universal moral standards, that ethics is without foundations, and that moral differences cannot be resolved" (Tong, 2007, p. 7).

The response to this criticism is easy. Ethics and morality are not sciences. Answers to ethical issues are not always black and white. Scholarly discourse within the field of ethics provides a vast range of opinions, insights, commonalities, and differences. This richness of views only strengthens our moral judgments to the tough bioethical problems and injustices that are found in the world of medicine and research. Rosemarie Tong (2007) states, “[Ethics] is an art that requires every ounce of moral imagination, emotion, and thought we can muster” (p. 9).

Summary

Bioethical feminist theory is a rapidly developing area of philosophical specialization. This is a field that tries to offer concrete practical advice that might not be readily inferred from abstract theories. Women are more often patients in the United States and have more physician contact than men (Horton, 1992). Even when women are not seeking medical advice for themselves, they are often the ones that must make medical decisions for others. They have made those medical decisions as mothers, wives, sisters, partners, and daughters. Bioethical feminist theory provides a voice for those women. The bioethical feminist voice not only analyzes a paternalistic medical system, but also offers medical counsel and moral reasoning with women as the central participants.

The most controversial issues of the twenty-first century are related to women and their bodies. Assisted reproduction, surrogacy, abortion, birth control methods, the increasing number of Caesarean sections, consumption of cosmetic surgery, fetal screening, and female genital circumcision are only a few of the pressing issues that are hotly contested but widely practiced. Ethical and legal rules on all of these issues will affect women first and foremost, and analysis of such rules must attend to the gender inequalities they may reinforce or create. This is the objective of bioethical feminist theory.

Susan Wolf (1996) has stated, “Bioethics cannot afford to overlook half the world, to ignore the pervasive effects of gender, and to avoid the feminist literature transforming the disciplines that make up this field” (p. 32). Modern bioethics is committed to protecting the health and interests of the patient and the research subject from harm by the physician and the medical researcher. Modern bioethical feminist theory has extended this commitment to alleviating the oppression and inequalities of oppressed women and children in the medical field. Rosemarie Tong has written, “Just because an approach to bioethics is gendered does not mean it is sexist” (1996, p. 83).

CHAPTER 3

REVIEW OF LITERATURE

Since the approval of the HPV vaccine by the FDA in June of 2006, there has been a plethora of journal and newspaper articles outlining the arguments for and against a government mandate and the efficacy of the new immunization. Currently, only two books have been written specifically discussing the HPV vaccine.

When one looks at the current literature regarding the HPV vaccine, several themes are evident. The first theme has dealt with the political controversy that commenced as soon as the state governments insisted on mandating the HPV vaccine for adolescent girls. The second theme has focused on the rebuttal to the government by parents, religious leaders, and bioethical feminists, which causes a social/ethical controversy to occur. A third theme that has surfaced in the literature is the worry about increased sexual promiscuity among adolescent girls if they receive this vaccine. This theme has both social and ethical underpinnings. Parents are afraid that they are sending the wrong message to their daughters if they have them vaccinated against an STD.

The purpose of this literature review was to provide an overview of these three themes and how these themes align with my investigation of mandating the HPV vaccine for adolescent girls. When the literature was reviewed, it was evident that authors came from a political, medical, social, or ethical stance. There currently is no piece of literature that incorporates the four stances and melds them into one body of literature. My theoretical inquiry was an attempt at melding the four stances to come to a decisive conclusion about why there has been such a huge controversy over mandating the first vaccine ever produced to prevent cancer.

Scope of Literature Review

The literature review for this theoretical inquiry surveyed significant literature published about the HPV vaccine. The literature for this review included works acquired from the Georgia Southern University Library, books used during my doctoral coursework, scholarly journals, newspapers, GALILEO database, and the websites for the Centers for Disease Control and Prevention and the United States Department of Health and Human Services. The majority of sources used were published within the last 5 years given the recent development of the HPV vaccine. A wide variety of sources were necessary in order to gain a complete picture of the political, social, medical, moral, legal, and bioethical dilemmas involved with the vaccination of adolescent girls against HPV.

Efficacy of the HPV Vaccine

Before discussing the three themes that have emerged when reviewing the HPV vaccine literature, I feel a review of the literature that discussed the HPV vaccine's efficacy was important to include in this section of the inquiry.

HPV is the underlying cause of virtually all cervical cancer diagnoses in women (Cutts, Franceshi, Goldie, Castellsague, de Sanjose, et.al, 2007). Each year in the US, cervical cancer is newly diagnosed in approximately 10,000 to 11,000 women, and over 3,000 women die from the malignancy (Krishnan, 2008). Even more staggering is the total number of HPV-associated conditions in both males and females. A total of 2.3 to 2.8 million cases each year are related to an infection with HPV (Krishnan, 2008). These cases range from mouth and throat cancers, penile cancer, vaginal cancer, vulvar cancer, anal cancer, cervical cancer, recurrent respiratory papillomas, cervical dysplasia, and genital warts (Krishnan, 2008). Dr. Shobha Krishnan has asserted, "The medical costs associated with treating HPV-related diseases in the United States

are second only to the costs created by HIV/AIDS” (2008, p. 49).

The World Health Organization (WHO) reported that cervical cancer is the most common cancer affecting women in developing countries (2007). It has been estimated that in 2005, cervical cancer killed 260,000 women, of whom 80% occurred in developing countries (WHO, 2007).

Recently, a vaccine that has the potential to prevent certain HPV infections, and hence reduce the incidence of cervical cancer and other anogenital cancers, has been licensed. The FDA approved Merck’s HPV vaccine, Gardasil[®], in June 2006. Another HPV vaccine called Cervarix[®] (produced by the drug company GlaxoSmithKline) is in advanced clinical testing. Gardasil[®], historic in that it is “the first vaccine explicitly designed to prevent cancer induced by a virus,” provides hope that the burden of HPV-related illness may be reduced (Baden, Curfman, Morrissey, & Drazen, 2007, ¶ 2). Clinical trials have shown the HPV vaccine to be safe and effective at preventing HPV infections that are commonly associated with the development of cervical cancer, as well as other HPV-related cancers and warts (Cutts et al., 2007). Physician Angie Goeser of the Creighton University School of Pharmacy and Health Professions wrote an article in *American Family Physician* outlining the HPV vaccines effectiveness. Dr. Goeser (2007) has stated:

Four studies enrolling more than 20,000 females 16 to 26 years of age who were free of HPV infection showed that only 2 of 7,858 patients who received all three doses of the HPV vaccine developed cervical intraepithelial neoplasia (CIN) grades I, II, or III because of one of the 2 strains of HPV; this was compared with 83 of 7,861 patients receiving the placebo (0.05 percent versus 1.1 percent, respectively). (p. 573)

These trials have demonstrated at least 95% efficacy in preventing disease related to four types

of HPV: types 6 and 11, which cause genital warts, and types 16 and 18, responsible for 70% of cervical cancers (Atkinson, Hamborsky, McIntyre, & Wolfe, 2008).

The very high clinical efficacy in women without prior HPV infection, and the lower efficacy among those already exposed to HPV, shows that vaccinating girls before they are exposed to HPV would have the greatest impact (WHO, 2007). The vaccine is most effective when administered in childhood, before initial exposure to HPV, which typically occurs shortly after the onset of sexual activity (Krishnan, 2008). Accordingly, the CDC's Advisory Committee on Immunization Practices (ACIP) has recommended routine vaccination of adolescent girls aged 11 or 12 years old, although the vaccine may be given as early as 9 years of age (CDC, 2009a). ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases.

The duration of the vaccine's protective effect is unknown, although studies have found no evidence of waning immunity or decline in efficacy for prevention even 4 to 5 years after administration of the vaccine series (Cutts et al., 2007). Once the initial vaccine series has been completed, booster doses are not currently recommended by ACIP. As studies progress and continuing research data is collected, this recommendation could be altered and booster shots may be required to enhance immunity.

Dr. Goeser (2007) has asserted, "Clinical trials have not yet identified serious safety issues with the HPV vaccine" (p. 573). Adverse reaction to the HPV vaccine administration has been limited to local reactions at the site of injection such as pain, swelling, or redness and to minor symptoms common to most any vaccine administration as syncope, nausea, dizziness,

malaise, and muscle aches. According to Atkinson et al., “These symptoms occurred with equal frequency among both vaccine and placebo recipients” (2008, p. 121).

The medical community has raised several major concerns regarding the HPV vaccine. Physicians George Sawaya and Karen Smith McClune, associate professors in residence in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco, wrote an article in the *New England Journal of Medicine* expressing their concern. They believe there are several unanswered questions regarding the HPV vaccine. First, the studies involving the HPV vaccine have, out of necessity, used pre-invasive cervical lesions (specifically CIN II and III) as surrogates for the primary result of interest – cervical cancer (Sawaya & Smith-McClune, 2007). Because of the low incidence of cervical cancer, the FDA considers CIN II and III to be acceptable outcomes for cervical cancer. A study using cervical cancer as the primary outcome would take years to complete because of the delay between HPV infection and cervical cancer. Furthermore, a study allowing CIN lesions, detected through Pap screening, to progress to malignancy would be unethical. Due to the practical necessity of using substitute outcomes, the ultimate question of whether HPV vaccination prevents cervical cancer is still in question and will require long-term observation of a large number of vaccinated women.

A second concern involves the potential unintended consequence of vaccination. Currently, the vaccine protects against only two of the several HPV types known to cause cervical cancer. With widespread vaccination, other cancer-inducing HPV types may emerge as significant causes of cervical cancer (Sawaya & Smith-McClune, 2007). Continued analyses of data from ongoing clinical trials “will be important to determine the effect of vaccination on rates of pre-invasive lesions caused by non-vaccine HPV types” (Sawaya & Smith-McClune,

2007, p. 1993).

A third concern is that the vaccine is not licensed for use in males although data on immune response and safety in males aged 9-15 years are available, efficacy studies have not been completed (Markowitz, 2007). Males, of course, are not susceptible to the most significant adverse consequences of HPV infection – cervical disease – but they are susceptible to genital warts and cancers of the penis, anus, and oropharynx. Each of these cancers has been associated with HPV infection and may be preventable with vaccination (Cutts et al., 2007). In addition, vaccination of males could enhance “herd immunity” and reduce the number of cervical infections in women, since males are frequent carriers of HPV infection. On the other hand, “mathematical modeling has shown that, if vaccine coverage [of females] is high, vaccination of males in addition to females will offer little additive benefit in preventing HPV-related cervical disease” (Saslow, 2007 p.). Bioethically speaking, I found Saslow’s deduction using mathematical modeling unfounded and discriminatory especially when our history with the rubella vaccine was reviewed and the possible benefits of the HPV vaccine for men.

We can learn from our experience with rubella vaccination. When effective rubella vaccine became available in the 1970s, some public health authorities chose to vaccinate only the girls, in some cases not until their early teens (Allen, A., 2007). This seemed reasonable because the main deleterious consequence of rubella infection was fetal rubella syndrome, a major cause of devastating birth defects. Vaccinating women of childbearing age should have been sufficient (Allen, A., 2007). However, experience, best documented in Sweden, showed that sex-specific vaccination was not an effective policy. Only when boys and girls were vaccinated in the first years of life did rubella and fetal rubella syndrome essentially vanish (Boettinger & Forsgren, 1997).

Clinical trials to date have focused on females because women suffer most from the pathology of HPV infection. Males, however, are the carriers of HPV and are responsible for infecting their female partners. With the notable exception of genital warts and some cases of penile and anal cancer, there is little pathology associated with HPV in heterosexual males (Jansen & Shaw, 2004). HPV is very difficult to detect in this population. This is partly because of the lack (until recently) of an acceptable method of sampling. Men having sex with men do show an increased risk of anal cancer (Krishnan, 2008). The cells that line the anal canal have similar features to the cells that form the cervix. These cells, in both the anus and cervix, are the most frequent site of HPV infection. Since vaccines work best when given to large proportions of the population (provide herd immunity), vaccination trials to show some efficacy in men are currently being reviewed by the FDA. An FDA advisory panel recently voted in favor of the safety and efficacy of Gardasil[®] to inhibit genital warts in boys and men ages 9 to 26 (Singer, 2009). The FDA typically follows the recommendations of the advisory panels on drug approvals, but a determination on the marketing of the vaccine for boys and men has yet been made.

Dr. Goeser (2007) has concluded, “The HPV vaccine is safe and effective in preventing genital warts and cervical changes that may lead to cervical cancer” (p. 574). Vaccines that protect against HPV types 16 and 18 have the potential to reduce, but not eliminate, the risk of cervical cancer (WHO, 2007). Women will still be at risk from other high-risk types of HPV, and other interventions, including cervical screening, will be required.

The Political Theme

The vast majority of literature written about the HPV vaccine relates to the current controversy surrounding the government’s attempt at mandating the vaccine for preteen girls.

Given the controversial nature of the HPV vaccine and the infection it is designed to prevent, there are several different cultural and political elements involved with the widespread administration and promotion of the product. One major political issue is the possible mandating of HPV vaccination around the country. This possibility has completely overshadowed the purpose of the vaccination, which is preventing cervical cancer. Several different areas in the United States have or have tried to create legislation regarding the required administration of this vaccine. R. Alta Charo, a professor of law and bioethics at the University of Wisconsin, wrote an article describing the current feeling as it relates to politics and the HPV vaccine. Professor Charo (2007) has stated:

Cancer prevention has fallen victim to the culture wars. Throughout the United States, state legislatures are scrambling to respond to the availability of Merck's human papillomavirus vaccine, which has been shown to be effective in preventing infection with HPV strains that cause about 70% of cases of cervical cancer. (p. 1905)

This statement has implied the success or failure of this vaccine was not only based on medical facts but also on impressions and behaviors of different cultures. Professor Charo believes that access to the vaccine has become more of a political issue than a public health issue. She has asserted, "...concern has focused on a purported interference in family life and sexual mores. This concern has resulted in a variety of political efforts to forestall the creation of a mandated vaccination program" (2007, p. 1905). Numerous pieces of legislation regarding the HPV vaccine are being created and considered all over the United States. Only 3 months after the vaccine received approval from the FDA, the Michigan Senate became the first state governing body to propose legislation (Senate Bill 1416) that the HPV vaccine be compulsory for young girls entering middle school (Colgrove, 2006). The bill has not been enacted.

The first US state to enact a mandate was Texas. Texas governor, Rick Perry, issued an executive order in February 2007 requiring that all adolescent girls be vaccinated against HPV. The Texas House and Senate unanimously overturned the order in April 2007 due to the backlash of fellow politicians, civil rights groups, and Texas parents.

The most recent literature suggests states are still in the process of mandating this vaccine. According to National Conference of State Legislatures (2009), legislators in at least 42 states and Washington, D.C. have proposed HPV related legislation or resolutions. Some states are experiencing high approval for such legislation. Currently, 20 states have enacted legislation that would either require, fund, or educate the public about the HPV vaccine: Alaska, Colorado, Indiana, Iowa, Maine, Maryland, Michigan, Minnesota, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Texas, Utah, Virginia, and Washington (National Conference of State Legislatures, 2009; see Appendix A). Some states are still facing strong opposition for a school mandate. For example, New Mexico was able to successfully pass a bill (Senate Bill 244) through their state legislatures, but the mandate was vetoed once it reached the governor. Currently, New Mexico requires insurance plans in the state to cover the vaccine for girls between the ages of 9 and 14 (National Conference of State Legislatures, 2009).

Professor Charo has contended that states have the right to require people to be vaccinated. She has asserted (2007), "...both federal and state court decisions have consistently upheld vaccination mandates for children, even to the extent of denying unvaccinated children access to the public schools" (p. 1906). The literature supports that HPV vaccination mandates, which are aimed more at protecting the recipient than at achieving herd immunity have been attacked as an unwarranted intrusion on individual and parental rights (Charo, 2007; see also

Colgrove 2006; Daley & McDermott, 2007; Krishnan, 2008; Savage, 2007; Thomas, 2008). This has placed parents and lawmakers in a very complicated state of affairs. They can both deny sexual activity of teenagers and not promote vaccination, or they can promote vaccination that will spare lives while possibly giving teenagers a sense that their sexual activity is expected and in some way approved by adults. Many legislatures and family members seem more focused on the possible implications this vaccine could have on the sexual activity of adolescent girls. According to Professor Charo (2007), “Opposition seems based on the concern that to recognize the reality of teenage sexual activity is implicitly to endorse it” (p. 1907). Opponents have claimed that the HPV vaccine will change the onset and frequency of sexual activity in girls. However, this claim is not supported by empirical evidence and may be based on misconceptions and moral convictions (Monk & Wiley, 2006). The CDC has reported that it is unlikely that sexual activity will increase among teenagers as a result of the HPV vaccine (Kaiser Family Foundation, 2006). Moreover, fear of an STD has not been the primary reason for adolescents not to engage in sexual activity (Krishnan, 2008). Specifically, empirical research has found that distributing condoms in schools and increasing the availability of the morning-after pill are not associated with younger sexual debut or an increase in sexual frequency (Kirby, Brener, Brown, Person, & Harrist, 1999).

Legislative efforts to pass a mandate for adolescent girls are in line with the Advisory Committee on Immunization Practices (ACIP) of the CDC’s recommendations. The recommendations have stated that the HPV vaccine should be administered on a routine basis to all healthy 11- and 12- year-old girls, although the vaccine is approved for use as early as 9- years- old (Colgrove, 2006). Individual state requirements for childhood and adolescent vaccination varies as to the range of communicable diseases but are often based on ACIP

recommendations. Professor Charo (2007) has written, “School-based immunization requirements represent a key impetus for widespread vaccination of children and adolescents and are enforceable even when they allegedly conflict with personal or religious beliefs” (p. 1906). This statement brought up the question as to whether mandating the HPV vaccine has violated a girl’s constitutional right to autonomy. Beuchamp and Childress have stated, “Personal autonomy is, at a minimum, self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice” (2001, p. 58).

Tracy Solomon Dowling (2008), a JD candidate from Boston University School of Law, investigated the constitutionality of mandating the HPV vaccine, Gardasil®. She began her discussion summarizing the current HPV vaccine climate. Dowling has stated, “Because this medical advancement has the potential to improve public health and decrease the number of cervical cancer victims, many want to mandate vaccination for all women through a major public health initiative” (2008, p. 66). But do states have the constitutional right to require such a mandate for a disease that is not spread through casual contact? Dowling (2008) has asserted:

States have the constitutional right through their police powers to mandate vaccines in specific circumstances: if a public health necessity exists, if a reasonable relationship between the intervention and a public health objective exists, and if the intervention is proportional to the risk. (p. 66)

I disagree with Dowling; I do not believe individual governing states have a constitutional right to mandate the HPV vaccine. I have discussed my reasoning in chapter 6.

Even though Dowling believes the HPV vaccine mandate is constitutional, she asserted, “state legislatures should not require it” (2008, p. 66). Her reasoning is based on the fact that

cervical cancer impacts only a small portion of the population. My question to Dowling is, “What would constitute a large portion?” According to the CDC, in 2005, 11,999 women in the U.S. were diagnosed with cervical cancer, and 3,924 women died from the disease (2009b). Cervical cancer is the second leading cause of cancer deaths in women; the first being breast cancer (Krishnan, 2008). Globally, cervical cancer is the leading cause of cancer deaths in women (WHO, 2007). Dowling believes that it is unnecessary to mandate the vaccine when it “benefits only a limited number of individuals” (2008, p. 66). Would her opinion change if she were one of those “11,999 individuals?” She only justifies a mandate if the “collective benefits of mandatory vaccination outweigh the costs” (2008, p. 66). Mandating the vaccine would come at high costs because it is the most expensive vaccine available. Dowling (2008) has written, “The drug itself is extremely expensive, imposing a high financial burden on an already cost-inflated health care system” (p. 66). A projected cost effectiveness study was performed using a computer-based model and published in the *Journal of the National Cancer Institute* in 2004. Goldie et al. (2004) have stated, “Our results indicate that the addition of an HPV 16/18 vaccine to current cervical cancer screening in the United States has the potential to be a cost-effective use of health care resources” (p. 612). According to Jonathan Temte of the University of Wisconsin School of Medicine and Public Health, “HPV infection accounts for expenditures of more than \$2 billion per year and significantly affects patient privacy and comfort” (2007, p. 117). Dowling cannot determine if the cost of vaccinating adolescent girls outweighs the cost of treating HPV induced cancers. Cutts et al. (2007) has asserted:

The estimated costs of and benefits from HPV vaccine need to be compared to those of other interventions. The magnitude of benefit in a specific country will depend on the incidence, mortality and treatment costs of disease attributable to the HPV types against

which the vaccines protect, as well as on the vaccine efficacy, achievable coverage and duration of protection. (p. 722)

The administration of the HPV vaccine is only 3 years old; long-term data on the vaccine's efficacy and duration of protection are unavailable so a true cost analysis is not currently available.

The last point Dowling discusses in terms of not mandating the HPV vaccine is the fact that it would violate one's autonomy. Dowling (2008) has stated, "Mandatory vaccinations restrict privacy rights and ownership of one's body, adding non-monetary costs that are critical to any evaluation of mandatory legislation" (p. 66). I agree with Dowling on this point. HPV is contracted almost exclusively by sexual contact. HPV does not fall into the same category as pertussis or measles, which are contracted by coughing and sneezing.

Since the landmark 1905 decision by the United States Supreme Court in *Jacobson v Massachusetts* upholding the state's compulsory vaccination law during the Boston smallpox epidemic that began in 1901, the federal and state courts have consistently supported vaccine mandates for both adults and children (Gostin, 2005). In the conflict between individual liberty and the common good, the law tends to favor the common good, at least in terms of protecting public health (other examples include laws mandating sanitation, animal control, and quarantines). Although the law does not allow for an individual to be vaccinated against his or her will, it does allow for punishment of those who refuse to comply. In the case of childhood vaccines, the typical punishment is denying access to public schools.

The constitutionality of mandating the HPV vaccine is based on the threat HPV-related illness poses to the general public, and "to the extent that required HPV vaccination is an example of state paternalism rather than community protection" (Charo, 2007, p. 1906). While

vaccines are designed to protect the individual, the development of herd immunity that results from large numbers of individual vaccinations serves an even more important role in protecting the population as a whole from infection. This is the “so-called” basis for the political drive to mandate the vaccine – protect the public. If this is the basis for mandating the vaccine then why are boys not vaccinated? Why only girls? In the critical analysis section I dissect this reasoning by answering this question. I also take a look at the link between the politicians who have pushed hard for the mandate and their relationship to the drug company, Merck, which produces the immunization. Another question that is addressed in the critical analysis section is the fact that the brunt of HPV-related illness is carried by the less influential members of society – those of ethnic minorities or low socioeconomic status. If we have the statistics that prove that Hispanic and African American women have higher rates of cervical cancer, then why is the drug so expensive? How can Merck, in good faith, market a drug for a disease of disparity and charge over \$350 for its administration. How can the HPV vaccine be made more affordable so that the girls who really need to be immunized not only have access to the drug, but are educated about their reproductive health?

The Social/Ethical Theme

Mandating Gardasil[®] also raises social/bioethical issues. Under current proposals, mandates would force people to undergo drug therapy (vaccination), when they have no disease, under the presumption that they might get a disease based on future behavior. One might argue that we do have, as public policy, mandatory vaccinations for some infectious diseases like mumps, measles, and rubella (MMR). The difference is that MMR are contagious diseases that can be caught by sitting next to an infected person in a classroom. HPV is not spread by casual contact. Jon Abramson, the chairman of the ACIP of the CDC, explains that protecting children

against a virus that is spread by sexual activity is different from preventing the spread of measles (cited in O'Beirne, 2007). Abramson believes that mandating the HPV vaccine "is a much harder case to make, because you're not going to spread it in school unless you are doing something you're not supposed to be doing in school" (cited in O'Beirne, 2007, p. 20). Non-vaccinated students would pose no risk to others while in school.

In addition to specific parental concerns regarding the HPV vaccine as it pertains to adolescent sexuality, HPV vaccine mandates also face opposition from an increasing number of parents who resist vaccination efforts in general. Arthur Allen, a former Associated Press foreign correspondent and author, wrote a book entitled *Vaccine: The Controversial Story of Medicine's Greatest Lifesaver*. In his book he has discussed the inflammatory history of vaccines. Arthur Allen (2007) has asserted, "There was a time not so long ago when nearly all Americans, grateful for the defeat of polio by Jonas Salk's famous shots, eagerly embraced vaccination" (p. 14). Today, however, vaccine-preventable disease has become less common than adverse reactions from vaccination itself, leading many parents to believe that the cure is worse than the disease: the fainting spell or sore arm that their child experienced as a result of vaccination is fresh on their minds, while the scourge of paralysis from polio is a distant memory (if that). In addition, many individuals fall prey to the tendency to attribute any number of ailments to a vaccine received days (or weeks) prior. Perhaps the most prominent example is the commonly stated belief that an individual contracted his or her flu from the influenza vaccine, despite there being vast numbers of noninfluenza respiratory infections that circulate during cold and flu season and no real basis for the notion that the inactivated viral particles in the influenza vaccine can cause the flu.

More troublesome, is the trend to attribute blame for diseases that have no known

cause, to vaccination. Some advocacy groups are now implicating vaccines as the cause of a wide range of illnesses—including, among others, asthma, attention deficit disorder, chronic fatigue syndrome, diabetes, inflammatory bowel disease, and sudden infant death syndrome (Infectious Diseases in Children, 1999). Perhaps the most controversial of these implications is the link between vaccination and autism. Thimerosal, a mercury-containing preservative, is used in several vaccine formulations. Although the assertion is not supported by scientific research, many parents and various anti-vaccine advocacy groups implicate thimerosal as a cause of autism. Although the HPV vaccine does not contain thimerosal, an emerging mistrust of scientific claims of safety could play a role in the public's slow acceptance of new vaccines, regardless of their thimerosal content.

Bioethical feminists have brought up another ethical issue at the forefront of the debate. Currently, the vaccine is gender-specific, recommended for girls only. Even though cervical dysplasia and cervical cancer are the most widely recognized disease caused by HPV, the virus does not just present a risk in women. HPV can cause significant health risks in men, too. Krishnan, a board certified gynecologist and family practice physician, has stated, “HPV is responsible for causing genital warts and penile, anal, mouth, and throat cancers in men” (2008, p. 117). Furthermore, in the majority of cases, HPV is spread to women through sexual contact with men. Therefore, an understanding of HPV infections in men is critical in reducing the risk of transmission to women (Krishnan, 2008). So the bioethical question has become, “Why are men not being targeted equally by the HPV prevention program and Merck's ‘One Less’ campaign when they play such an integral role in transmission of the disease?” According to Krishnan (2008), “The answer might lie in the sheer lack of information. While a wealth of information about HPV in women is available, research in men has so far only scratched the

surface” (p. 118). Clinical trials looking at the vaccine’s efficacy in adolescent boys are underway (Udesky, 2007). The vaccine is currently not recommended for boys because the safety and effectiveness has not been proven.

There is also a concern from the medical community, that there will be a drop in the number of women getting annual Pap smears if the HPV vaccine is mandated. Ian Anderson (2002) from the University of Leeds has stated:

If just women are vaccinated against HPV, there will be a negative effect on smear attendance. Many women already find cervical smear testing unpleasant and if they think that they are immune from cervical cancer, they may be disinclined to continue with them, despite the fact that routine gynecological examination allow the medical profession the opportunity to inspect for other problems and to educate women about pregnancy and sexually transmitted diseases. (p. 2)

Education will be a vital part of a successful immunization program. Women need to understand that just because they have been immunized, they are not immune to cervical cancer. Gardasil® only protects women from two of the 30 types of HPV that cause cancer. Yes, those two types cause 70% of all cervical cancers, but there is still a 30% chance of getting the disease. An annual Pap smear is still recommended to detect for abnormal cervical cells that could lead to cancer.

The swiftness that pro-vaccine advocates are pushing for a mandate is alarming some, especially parents who do not want their daughters used as guinea pigs. Merck cannot guarantee there will be any long-term health consequences, as have occurred with other vaccines. They also cannot guarantee long-term protection. Although the side effects of the vaccine are quite low, thus far subjects have been followed for only 4 years. Merck has agreed to continue to conduct

several studies following licensure to further evaluate general safety and long-term effectiveness (Nicoletti & Tonelli, 2006). Barbara Loe Fisher, co-founder of the National Vaccine Information Center, is very concerned. She recently has stated, “[There is] a thin base of testing upon which to make this vaccine mandatory” (cited in Houppert, 2007). William Schaffner, a chair of the Department of Preventative Medicine at the Vanderbilt School of Medicine, has pointed out, “There is merit in not immediately mandating the vaccine. Let’s do some surveillance first, let’s be a little prudent” (cited in Udesky, 2007, p. 980). The best line of reasoning for a delayed approach is the history behind the first vaccine against rotavirus, a virus that causes severe diarrhea in children. After widespread use of the vaccine, an unsuspected side effect occurred; intussusception, a life-threatening bowel disorder, occurred in some children and the vaccine was removed from the market (Udesky, 2007).

In January of this year, The American Academy of Pediatrics and the Association of American Physicians and Surgeons voiced concerns over patchy reimbursement. Dr. Goodman, a pediatrician, had stated, “So far I have not seen any reimbursement from insurance companies for the vaccines I have administered, but I guess time will tell” (personal communication, July 3, 2007). This attitude may seem cavalier to some, but doctor offices must purchase vaccines and wait for reimbursement from either the government or private insurance companies. Some physicians have argued that the rising costs of vaccines and the rising number of new mandatory vaccines make it increasingly difficult for them to purchase vaccinations initially and that they net a loss due to insufficient reimbursement from insurers (Javitt, Berkowitz, & Gostin, 2008).

Another concern was the absence of safety data in the target population and the knowledge of immunizing girls against a disease that is now less prevalent in the U.S. and that, in any case, does not develop until later in life. This had prompted the question – “Will immunity

last?” Preteens are the preferred demographic for vaccination, but only 1,184 (5%) of the 25,000 people participating in Gardasil[®]’s clinical trials were from this group (Flogging Gardasil[®], 2007). Critics could, therefore, claim that an “untested” product was being foisted onto America’s children, and Merck did not have a strong enough data based case to allay parents’ fears concerning vaccine safety. Merck’s quest for compulsory immunization so soon after approval also broke with precedent for vaccines, which are usually in use for years before being mandated.

Barbara Fisher insists that making the HPV vaccine compulsory violates parents’ rights. “We are not against vaccine availability, just vaccine mandates” (cited in Houppert, 2007, p. 18). While she concedes that every governing state but two has some kind of opt-out clause for parents who object to the vaccine for health, religious, moral, or ethical reasons, she believes parents who refuse immunization are harassed (Houppert, 2007). Texas state senator Glenn Hegar introduced legislation to reverse Governor Perry’s order on the grounds that research trials are still underway and “such mandates take away parents’ rights to make medical decisions for their children and usurp parental authority” (O’Beirne, 2007, p. 20).

Neal Halsey, a professor in the department of International Health and Pediatrics at John Hopkins’s Bloomberg School of Public Health, worries about the logistics of mandating Gardasil[®]. He has asserted, “I think it’s premature to require this for school entry, because we don’t have good systems in place to make sure we can deliver this to all girls” (cited in Houppert, 2007, p. 20). If the government is going to mandate this vaccine, then public health officials need to make sure the supply can be maintained, and that there are mechanisms in place to insure that the drug will make it to all those in need. According to Halsey, the U.S. Health Department does a great job of getting babies and little children immunized in this

country because well-baby visits insure regular contact with doctors and because the government has a system in place to make sure all young children, even those without insurance, can get the required shots. “But we are doing a terrible job delivering vaccines to adolescents, due to the lack of infrastructure at the CDC and state health departments” (cited in Houppert, 2007, p. 20). He worries those rushing school immunization requirements for the HPV vaccine will just overwhelm an already stretched system. Halsey’s sentiment is one of efficiency not effectiveness; this devalues the lives of girls. If the government mandates the HPV vaccine, a strategy of dispersal will need to be set in place. Why not allow the vaccine to be administered in the school’s nurse’s office? It seems reasonable that if the vaccine is mandated for school entrance, why not kill two birds with one stone?

Will the HPV Vaccine Promote Adolescent Sex?

Mandating Gardasil[®] has also been criticized by family organizations, like Focus on the Family, abstinence-only hardliners, evangelical groups, and right-wing conservatives. They are touting the familiar argument: Safe sex leads to more sex. Krishnan (2008) has asserted, “Many parents and religious leaders wonder whether the vaccine is just a ‘quick fix’ to address the consequences of behavioral choices” (p. xi). Is giving a vaccine for a sexually transmitted disease tantamount to promoting sexual activity? This argument has been raised before concerning comprehensive sex education (as opposed to abstinence only education) and the distribution of condoms to adolescents in an attempt to reduce the risk of more immediate and threatening adverse health outcomes such as AIDS or pregnancy. But research suggests that just the opposite is true: Comprehensive sex education strategies may actually “delay initiation of sexual intercourse, reduce frequency of sex, reduce frequency of unprotected sex, and reduce the number of sexual partners” (Bleakley, Hennessy, & Fishbein, 2006, p. 1153).

Similar to the debate surrounding the distribution of condoms to prevent unwanted teen pregnancies or HIV and other sexually transmitted diseases, the use of the HPV vaccine to prevent cervical cancer has passed from the public health arena into the political arena. This is particularly true given the need to vaccinate children. If the HPV vaccine were equally effective before or after HPV exposure, then it could be equally efficacious as an adult immunization, and perhaps much of the controversy would subside. As it is, however, HPV vaccine mandates have been attacked as “an intrusion on parental discretion and an invitation to teenage promiscuity” (Charo, 2007, p. 1907).

Proponents of the current political push for an abstinence-only approach to STD prevention argue that abstinence offers a practical and safe alternative that “undermines the argument for a state initiative that encourages vaccination” (Charo, 2007, 1907). But experience shows that abstinence-only approaches to sex education do not delay the age of sexual initiation, nor do they decrease the number of sexual encounters (Charo, 2007). A research study commissioned by the U.S. Department of Health and Human Services in order to evaluate the effectiveness of the \$50 million annual federal funding of abstinence education programs found that “youth in the [abstinence education] program group were no more likely than the control group youth to have abstained from sex, and among those who reported having sex, they had similar numbers of sexual partners and had initiated sex at the same mean age (Trenholm et al., 2007). According to the CDC, though only 13% of American girls are sexually experienced by 15 years of age, by 17 the proportion grows to 43%, and by 19 to 70% (Dailard, 2006). Professor Charo has pointed out that any sex education curriculum needs to begin before children begin to drop out where rates begin to increase during the middle school years. Charo (2007) has stated:

School-based programs are crucial for reaching those at highest risk of contracting

sexually transmitted diseases, and despite the relatively low rate of sexual activity before age 15, the programs need to begin with children as young as 12 years: the rates at which adolescents drop out of school begin to increase at 13 years of age, and younger dropouts have been shown to be especially likely to engage in earlier or riskier sexual activity (p. 1907).

Further evidence suggesting that current approaches to adolescent STD prevention are ineffective is a recent CDC study of 838 female adolescents participating in the 2003-2004 National Health and Nutrition Examination Survey (NHANES). This study revealed that approximately one in four females age 14-19 years is infected with one of four common STDs: HPV, Chlamydia, herpes simplex virus 2, or trichomoniasis (Hampton, 2008). The most prevalent STD found among the girls was HPV at a rate of 18.3% (Hampton, 2008).

Summary

A review of the HPV vaccine literature demonstrates the need for critical discourse when discussing the role of vaccines and healthcare. The debate seems to be more about politics than the health of our children. In my critical analysis chapter I sort out this debate to come up with a conclusion about what is the solution to this controversy.

In chapter 4, I have provided a synopsis for the politics behind vaccine mandates. I discuss the role of the CDC, how vaccines are approved, and how the FDA ensures vaccine safety.

CHAPTER 4

VACCINE POLICY: A BIOETHICAL SHOT AT YOUR RIGHTS

Vaccination is the single most cost-effective health intervention known to modern science and public policy (Russell, 1995). The United States, known for its commitment to one's individual freedom and rights, has taken an unusually aggressive stance with regard to vaccination. Since the Constitution did not grant to the federal government the power to enact health regulations, the individual states control compulsory vaccination programs. In some states the Department of Health and Human Services (HHS) decides vaccine policy; in other states, policy is legislated. In both instances, however, there is tremendous pressure to follow federal guidelines. State health departments depend heavily on federal dollars, which may be withdrawn if the state does not meet federal quotas. The power and prestige of the CDC and the FDA easily intimidate state legislators and even health care professionals who might otherwise deviate from the official path of the mandated vaccine schedule (Link, 2005).

When I have my daughter vaccinated against tetanus, which grows in soil and on rusty nails, and does not spread from child to child, I am protecting my child alone. But I also vaccinate her against measles, mumps, polio, pertussis, hepatitis, diphtheria, and pneumonia. In doing so I not only protect my own child, but also help eliminate the safe haven from which these organisms might launch an attack on somebody else's child, on a teenager whose immunity has waned, or an adult who has never been immunized. Public health policy recognizes that complete personal responsibility is unattainable. Within limits, we must all help look after one another – that is our social duty as fellow human beings.

Public health policy has played a large role in the health and welfare of each person in society. Public health policy has encompassed everything from clean water and air quality to the

mandating of bike helmets and immunizing our children. Health policy has helped increase the life expectancy from 47.8 years in 1900 to 78.1 years today (Kohrs, 2002). Many people have been saved from the horrendous cough of pertussis, the crippling effects of polio, and the devastating birth defects caused by rubella.

While many laws infringe on a person's rights under the Constitution, most governing states allow exemptions to the mandated vaccines. For example, 48 states allow exemptions for religious beliefs (Mississippi and West Virginia do not), 17 exempt for philosophical beliefs, and all states allow medical exemptions (Kohrs, 2002). Those claiming religious exemptions base their arguments on the right to free exercise of religion encompassed in the First Amendment. However, the U.S. Supreme Court has not recognized the First Amendment exemption to mandatory vaccination programs for dangerous diseases (Kohrs, 2002). The U.S. Supreme Court states, "We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate" (Kohrs, 2002, p. 241). Philosophical exemption is based on an individual's objection to vaccines for personal, philosophical, moral, or other beliefs. The medical exemption requires a written declaration by a licensed physician stating the vaccination is dangerous to the individual's health. The final verdict for these three types of exemptions is left in the hands of the courts. Throughout history, the courts have, in matters of health, consistently put the common good before individual rights.

There is no question the compulsory vaccination policy is a violation of a person's right to autonomy and privacy as stated by the Fourteenth Amendment, but we can thank this policy for the complete eradication of smallpox, with polio not far behind. It has also significantly reduced the incidence of several of the most devastating communicable diseases. We, as Americans, must realize that that the good of the many outweighs the interest of the few.

The Crossroads – Vaccine Compliance, Politics, and Controversy

Every man is entitled to his own opinions, but not to his own facts.

- Daniel Patrick Moynihan

Last month I took my 2-month-old daughter to the pediatrician for her check-up. She was due for her first set of vaccinations. The first government mandated vaccines are administered at the age of 2 months. There are six vaccines required: Hepatitis B, Rotavirus, DTaP (Diphtheria, Tetanus, & Pertussis), *Haemophilus influenza*, Pneumococcal, and Polio. Arthur Allen (2007) states, “In America, vaccination is the first act the state requires of a person” (p. 15).

Knowing I was writing this dissertation, I asked the pediatrician if she thought there was any harm to giving a 2-month-old so many vaccines at one time (six total would be given). I already knew the answer the pediatrician would politely tell me. She proceeded to explain that there is always a risk in administering any medicine, and each child reacts differently to drugs. Some have absolutely no side effects from the drug, some get a slight fever, and a few get violently ill or die. “A few get violently ill or die,” rolled off her tongue as if she were telling me a bedtime story. I thought to myself, “Boy, that was a textbook answer.” She had to tell me there is some risk to vaccinating children.

I then began to think about my Aunt Patricia. She was a wonderful woman with a really bad cough. In 1931, when Pat was only one-year-old, she caught whooping cough from an infected cousin. Although the vaccine was developed in 1914, Pat had not been immunized. From the day she was exposed to *Bordetella pertussis*, the bacteria that causes whooping cough, she was never the same. She spent her life coughing up blood and eventually had 2/3 of her lungs removed. Towards the end of her life she was on oxygen. I thought to myself, as I was standing in the pediatrician’s office, what would Pat’s life have been like if she had been vaccinated?

Would she still be with us? It was my relationship with Pat that taught me how important vaccines are to individuals and society as a whole. I then signed the vaccination waiver, took the CDC vaccine information hand-outs, and held my daughter's arms as the nurse injected her legs with possibly life-saving drugs.

According to the CDC's National Immunization Survey (NIS), childhood immunization rates remain at or near record levels, with more than 77% of children being fully vaccinated with all vaccines in the series of recommended immunizations (CDC, 2008b). Julie Gerberding, the CDC director, has stated, "The ongoing success of our nation's immunization program is largely dependent on the trust that parents put in the safety of vaccines and in those caregivers who administer them" (CDC, 2008b, ¶4). The issue of vaccine administration is more than a trust relationship between parents and the end of the needle. It is also a relationship of coercion.

The government and technocracies deploy three strategies to ensure compliance with vaccination mandates from the general public. The first strategy uses force and compulsion. Many of the early smallpox vaccination campaigns relied on real force often orchestrated by the military (Leach & Fairhead, 2007). On March 15, 1902 Reverend Henning Jacobson refused to be vaccinated against smallpox and he was convicted and fined \$5. In 1905, in the ruling in *Jacobson vs. Massachusetts*, the Supreme Court upheld the right of the city of Cambridge, Massachusetts to mandate vaccination against smallpox (Parmet, Goodman, & Farber, 2005). The high court rejected the contention that mandatory vaccination violated an individual's rights to due process and equal protection as guaranteed by the Fourteenth Amendment of the Constitution (Parmet et al., 2005). The court held that states may limit individual liberty in the service of well-established public health interventions. The court also ruled that the risk of injury from vaccination was small when compared to the substantial social benefits. I expound further

on this ruling by the Supreme Court in Chapter 6 when I discuss the constitutionality of mandating the HPV vaccine.

The second strategy links vaccination to rules of material benefits. For example, in the U.S., students are not allowed to enter public school without proof of vaccination. In France, immunization is a requirement for access to certain welfare and tax benefits.

The third strategy aims at instilling vaccination as a habit, and inculcating a desire for it. Leach and Fairhead (2007) has asserted, “The incorporation of vaccination into parents’ normal routines and practices is the goal of mandating immunizations, so that it becomes an unproblematic matter of unthinking and passive acceptance of community practices (social demand)” (p. 9).

These compliance strategies have not eliminated the antivaccination movement that seeks to stop vaccination, and its arguments cover the spectrum from reasonable discourse to hysterical paranoia. The antivaccination argument begins with vaccination being counterintuitive. Bioethically speaking, what sense does it make to inject a well baby with a potent, biologically active vaccine that contains elements of the very disease it is supposed to prevent? The vaccination is literally an infection with a variant of the disease-causing agent. It is also feared that vaccines contain poisons and chemicals, including mercury, formaldehyde, antibiotics, and aluminum salts (Link, 2005). Vaccines also contain material derived from animals, including cattle, horse, chicken, monkey, and duck. Some vaccines have been recalled or discontinued because they were toxic or ineffective. The rotavirus and Lyme disease vaccines are two recent examples. Some vaccines have serious side effects. Vaccines have been known to cause convulsions, fever, rashes, nerve and brain damage, and even death (Link, 2005).

The antivaccinationists also argue that the number of cases of common childhood diseases had dropped dramatically from the pre-vaccine era, and, on the other hand, even some vaccinated children get infected. More sophisticated critics are concerned about the age shift caused by vaccines. Natural infection often causes lifelong immunity, whereas vaccine-induced immunity tends to wear off. This results in a population of nonimmune adults, and many mild childhood diseases are more severe in adults. For example, they argue that the chickenpox vaccine is unnecessary and may cause an epidemic of adult shingles in years to come.

Politics and financial profits are entwined with medical policymaking. Those against mandatory vaccination argue that the medical establishment, the pharmaceutical industry, and political interest groups influence vaccine policies to favor their interests. This whiff of corruption further energizes the antivaccination group, reinforcing their resentment of the policy of mandatory vaccination. I provide some examples of this corruption later in the paper.

So why vaccinate? Vaccination saves millions of lives and prevents a world of suffering. We know that vaccines work. Epidemiological studies, clinical trials, antibody titers, and recurrence of disease when vaccination is discontinued all prove that vaccines work (Allen, A., 2007). None of them work 100 percent of the time; none of them are 100 percent safe. Each vaccine has unique problems and benefits. The reduction in the number of cases before the vaccine era was probably due to better hygiene, antibiotics, and better nutrition (Link, 2005). However, in all cases the common infections persisted at lower but significant levels until a vaccine became available. No disease has been known to disappear spontaneously (Allen, A., 2007). Now smallpox is gone; polio is not far behind.

Developing longer-lasting vaccines or developing boosters for adults can address the problem of age shift. The concern about autism and the many other unproven toxicities is usually

due to confusion about causality and coincidence. Autism typically starts at the age when immunizations are routinely administered so of course the two appear to be related, but are not (Link, 2005). The mercury story is complicated but moot in the United States because there is no longer mercury in the routine vaccines. The other chemicals and animal products are in trace amounts and harmless (Link, 2005).

Sometimes a vaccine is a victim of its own success. As the disease disappears, the side effects alone remain. Today's parents have never seen the horror of whooping cough or the grisly death of tetanus so their tolerance of vaccine side effects, like fever and soreness at the injection site, approaches zero. The controversy gets really heated when the issue is vaccine injury. How many infections or deaths prevented justify a death from a vaccine? Some would say it is never justified; better a thousand cases of measles than the life of one healthy child. Peggy O'Mara (1997) even goes so far as to have written, "It is immoral to risk the health of even one child in order to save the lives of many" (p. 3). To the medical scientist such a position is illogical, inhibits further medical advances, and denies children the freedom to grow up healthy. The pro and con sides of the vaccine debate, having staked opposing positions based on mutually exclusive premises, will likely span across another hundred years of controversy.

The Vaccine Machine – How Drug Companies Can Influence Vaccine Policy

As I stated previously, the CDC dictates the United States immunization policy. It appoints members of the Advisory Committee on Immunization Practices (ACIP), which then makes a schedule of vaccine recommendations and publishes it in the *CDC Morbidity and Mortality Weekly Report* (Schlafly, 1999). The "advice" of ACIP is what trickles down to a doctor's office or clinic. Members who serve on the advisory committees are made up of experts outside the government. On June 15, 2000 Republican congressman Dan Burton of Indiana

presided over the Government Reform Committee hearings on conflicts of interest in the vaccine approval process. Burton (2000) has affirmed:

The FDA and CDC rely on advisory committees to help them make vaccine policies that affect every child in this country. We've looked carefully at conflicts of interest. We've taken a good hard look at whether the pharmaceutical industry has too much influence over these committees. From the evidence we found, I think they do. (p. 4)

Rep. Burton learned that many advisory panel members had received research grants from drug companies, either for themselves or their academic institutions; others received money for speaking honoraria, travel funds or other benefits (Kirby, 2005). Some were found to even share patents on certain vaccines. Even though they were required to recuse themselves from voting on products in which they held a direct financial stake, the advisors could lobby colleagues in closed-door meetings (Kirby, 2005).

Pharmaceutical companies are big campaign finance contributors, having given \$44 million over the last ten years (Angell, 2005). FDA scientists who approve drugs or decide upon regulations are also current, past, or future employees of the drug industry (Allen, A., 2007). They are inextricably tied to the industry that they are supposed to be policing. What this means is that the FDA is effectively financed and staffed by the pharmaceutical industry. The agencies “work for” the industry, not for consumers, because consumers are not making campaign contributions nor are they arbiters of job security.

Burton believed the conflicts might have played a role in why so many new vaccines were added in quick succession to the immunization schedule, including the ill-fated Rotashield. Rotashield was a vaccine given to children against rotavirus, a diarrhea-causing colonist of the gut (Allen, A., 2007). ACIP placed Rotashield on the list of recommended vaccines on June 25,

1998. Rotashield was then pulled from the market on July 16, 1999 because it was found to cause intussusceptions, an inversion of the intestine within itself that sometimes required surgery and could even be fatal (Rennels, 2000). It was later disclosed that members of the FDA and CDC advisory committees who made decisions about what immunizations should be mandated owned stock in drug companies that made the vaccines (Kirby, 2005). Three out of five of the members of the FDA's advisory committee who voted for the rotavirus vaccine (Rotashield) had conflicts of interest that were waived (Kirby 2005). Rep. Burton (2000) has charged:

The entire process has been polluted and the public trust has been violated. No individual who stands to gain financially from the decisions regarding vaccines that may be mandated for use should be participating in the discussion or policy making for vaccines.

(p. 6)

Marcia Angell (2005) has contended, "The heavy hand of Big Pharma is felt at all levels of government" (p. 193). The "heavy hand" unfortunately includes the FDA and CDC. Even with corruption in the system it only behooves all involved to make sure vaccines are safe to administer to children.

How the FDA Ensures Vaccines Safety

First, do no harm.

-Hippocrates

The highest standards of safety must be required of vaccine manufacturers because the majority of vaccines are administered to healthy infants and children. The *Public Health Service Act* provides the federal government with authority to regulate biological products such as vaccines (Hargan, O'Brien, Sherman, & Benjamin, 2007). Vaccines are evaluated by the FDA-

specifically the Center for Biologics Evaluation and Research (CBER). The CBER requires drug companies to supply data on vaccine safety and effectiveness.

The first step to licensing a new vaccine is safety testing on animals. This step is called the safety trials. Animal safety tests usually come at the end of a long process of safety data collection that may include testing the product “*in vitro*” (i.e. in a test-tube) and using a computer program to simulate what might happen to the drug inside the body. The regulations on what safety data are required for a new product varies from country to country (and also from drug to drug). The FDA requires all new drugs, including vaccines, to be tested on animals before human trials may start. Generally, two or more species (one rodent, one non-rodent) are tested because a drug may affect one species differently from another. Only after successful animal testing has been done does testing in people begin.

A drug company that wants to begin clinical trials of a new vaccine must submit an Investigational New Drug (IND) application to the FDA. The IND describes the vaccine, the method of manufacture, and the quality control testing (safety trials) done prior to administering the vaccine to humans (CDC, 2001). The IND must also include the vaccine’s safety and ability to elicit an immune response in animals. Pre-marketing clinical trials usually occur in three phases.

Initial human studies, referred to as Phase I trials, evaluate basic safety and identify serious adverse effects, and immunogenicity or the ability to produce an immune response. These trials are small, between 20 and 100 patients, and last just several months. Phase II trials enroll up to hundreds of subjects and include dose-ranging studies. This phase can take up to 2 years to complete. Phase III includes several hundred to several thousand people and provides the critical documentation of effectiveness and important safety data required for licensing. But

until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, many vaccines undergo Phase 4 studies – formal studies on a vaccine once it is on the market. The government also relies on the Vaccine Adverse Event Reporting System (VAERS) to identify problems after marketing begins.

The FDA and CDC manage VAERS, a system the two agencies developed in response to the National Vaccine Injury Act of 1986. Anyone – physicians, nurses, vaccine manufacturers, patients, and parents – can report to VAERS an adverse event that may be associated with any vaccine. Susan Ellenberg, director of CBER’s division of biostatistics and epidemiology, has stated, “What we’re most interested in with VAERS is identifying any new problem, particularly serious problems, that might be so rare that it wasn’t noticed or detected during clinical trials” (cited in Stehlin, 1995). The Vaccine Datalink is another tighter program, administered by the CDC, with seven million HMOs that report vaccine events (Hargan et al., 2007).

On the surface, it may seem that approaching vaccine safety as a continuous process, always looking into problems and potential problems, implies that vaccines are unsafe. Jesse Goodman, deputy director for medicine at CBER, has stated, "It's actually a reflection of our ongoing commitment to safety, and to assuring the prevention of potentially lethal infectious diseases. It's also the nature of science to seek and implement improvements which make for safer and more effective medical products" (cited in Meadows, 2001, p. 18).

Since 1996, for example, CBER has licensed several acellular pertussis vaccines. Acellular pertussis vaccines use only parts of the disease-causing bacteria and are associated with fewer side effects than the whole cell pertussis vaccines that had been in use. In 1997, the ACIP recommended a switch from using the whole cell pertussis component of the diphtheria, tetanus, pertussis (DTP) vaccine to using acellular pertussis vaccines for all five doses in the

childhood schedule (Meadows, 2001, p. 18).

The National Institute of Allergy and Infectious Diseases (NIAID) sponsored clinical trials for some of the experimental acellular vaccines. "We set out to develop an improved vaccine that would be as effective as the standard whole cell vaccine but cause less extended crying, fevers, and other side effects," said Carole Heilman, director of NIAID's division of microbiology and infectious diseases (cited in Meadows, 2001 p. 18). CBER scientists also played a critical role by developing methods to evaluate the acellular vaccines, which helped them get to clinical trials faster.

There have been other recent policy changes to improve vaccine safety, including ACIP's 1999 recommendation to change from the use of oral polio vaccine (OPV) to the inactivated polio virus (IPV). OPV had been highly effective in controlling naturally occurring polio outbreaks, preventing thousands of cases of paralysis a year. But as a live virus, it mutated in extremely rare cases to cause polio itself. Continued use of OPV resulted in about 10 cases of paralytic polio each year among millions vaccinated and their contacts, according to William Egan, deputy director of CBER's Office of Vaccine Research and Review (Brotherton & Gold, 2008). Switching to the use of IPV eliminated this risk and was appropriate once epidemic polio was controlled.

"There are times when we also take action even when there is just the theoretical potential for harm," Goodman says (cited in Meadows, 2001, p. 18). Thimerosal, a mercury-containing compound, had been the most widely used preservative in vaccines. Its use in minute amounts helped to prevent bacteria from contaminating multi-dose vials of vaccines and other medicines, protecting against potentially serious infections. But thimerosal has been nearly eliminated from vaccines because of legitimate and growing scientific concerns about the

possible effects of mercury on the human nervous system (Link, 2005).

Even though there are no convincing data that show harm because of thimerosal in vaccines, the U.S. Public Health Service recommended moving rapidly to vaccines that are thimerosal-free. The FDA encouraged manufacturers to comply and set the highest priority for its reviews of such products. As a result, all recommended pediatric vaccines available are now thimerosal free or have greatly reduced thimerosal contents. In March 2001, the FDA approved a newly formulated version of Tripedia, a diphtheria, tetanus toxoids, and acellular pertussis (DTaP) vaccine, with only a trace amount of thimerosal (Link, 2005). Like any medicine, vaccines carry a small risk of serious harm such as severe allergic reaction. But experts point out that the risk of being harmed by a vaccine is much lower than the risk, which comes with infectious diseases (Allen, A., 2007).

Compensating for the Side Effects of Vaccines

Concerns over vaccine safety have the potential to derail immunization programs. This may, in turn, cause considerable harm through resurgence of disease as vaccination coverage falls (Brotherton & Gold, 2008). For example, fears the measles-mumps-rubella (MMR) vaccine might have caused autism resulted in the recent resurgence of measles in the United Kingdom (McIntyre & Leask, 2008). Thus, monitoring and ensuring vaccine safety is critical to the success of any immunization program.

There are two critical questions about a vaccine or any other medical intervention: 1) Is it effective? 2) What are the adverse side effects? (Angell, 2005). The scientific answer to these questions comes from clinical trials. When a new vaccine is first licensed, the majority of vaccine safety data is derived from Phase I, II, and III clinical trials. Marcia Angell (2005) has stated, “The clinical stage of drug development is regulated by the Food and Drug

Administration (FDA)” (p. 27). Specifically, the FDA’s Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Vaccine clinical development follows the same general pathway as drugs and other biologics.

The CBER was developed to help keep tabs on the side effects that vaccines cause. Vaccine regulation was once in the control of the National Institutes of Health (NIH). A reorganization of vaccine regulation took place after the Cutter incident in 1955. The Cutter incident was one of the worst pharmaceutical disasters in U.S. history causing several thousand children to be exposed to live poliovirus after being immunized (Allen, A., 2007). This watershed event in medical history, a disaster that could have “wrecked the polio eradication campaign and all vaccination programs, in fact inspired major reforms in the public health service, bolstering new structures that would serve the country well over the next five decades” (Allen, A., 2007, p. 199). Paul Offit (2005b) has stated, “The Cutter incident resulted in the first coordinated national response to a medical emergency and in the creation of a better system of regulating vaccines” (p. 1411).

The CDC has set up active disease surveillance units; investigations by the CDC’s new Epidemic Intelligence Service established the credibility of that group which would become the crown jewel of the agency. Seeing the need for better vaccine regulation, the government replaced the Laboratory of Biologics Control with the much larger Division of Biologic Standards and expanded the scientific staff from 10 to 110 (Allen, A., 2007).

In the early 1980s, following reports of harmful side effects after the administration of the DTP vaccine, numerous lawsuits were filed against vaccine manufacturers. Parents of children with severe vaccine-related injuries had few options to cope with random tragedy. Health insurance rarely covered long-term care. Thus, parents resorted to the courts, suing the

vaccine manufacturers for producing or distributing a defective vaccine or for failing to warn of the risks. The difficulty in predicting adverse reactions made it equally difficult to prove that the vaccine caused an injury. Vaccine manufacturers found these lawsuits oppressive. The possibility of losing even one expensive lawsuit made manufacturers nervous, given vaccines' relatively low profit margins. The number of domestic vaccine producers had been declining since the 1960s (Mariner, 1992). Public health officials worried that if manufacturers abandoned the vaccine market, the country might be left without an adequate vaccine supply. This litigation led to concerns about the continued viability of the U.S. vaccine industry.

In response, Congress created the National Vaccine Injury Act of 1986 as a compromise solution to 2 decades of controversy over whether and how adverse reactions to vaccines should be compensated. Among its provisions, the act established the National Vaccine injury Compensation Program (VICP). Those injured by vaccines can make claims against a special government fund. Congress fashioned this no-fault system to benefit people who suffer vaccine-related injuries (Vernick, Rutkow, & Salmon, 2007). "No-fault" means that compensation is provided without the need to show that a wrong was committed. To be eligible for compensation, a vaccine-related injury or death ordinarily must occur after the administration of a vaccine listed on a Vaccine Injury Table created by the law (Vernick et al., 2007). In addition, the petitioner must have suffered an injury listed on the table within a prescribed time frame. For example, to qualify for compensation following a tetanus vaccination, the injury must be recognized in the table and have occurred within 4 hours after the vaccine's administration (Vernick et al., 2007). Under the VICP, several types of compensation are available. Compensation can include medical expenses, loss of earning capacity, up to \$250,000 for pain and suffering, and attorney's fees (Mariner, 1992). Congress has established a federal \$0.75 excise tax per covered vaccine that

funds the VICP (Hargan et al., 2007). The VICP remains the model method for ensuring that all persons harmed by vaccines are compensated quickly and generously, while protecting companies that make lifesaving products from abuses of the tort system.

Summary – Our Best Shot

Does U.S. vaccine policy infringe on individual rights? Yes. Is there corruption in the organizations that regulate vaccine policy? Yes. Are vaccines 100% safe? No. Is there a bioethical concern with giving a perfectly healthy baby a drug to prevent a disease that he or she may come into contact in the future? Maybe. All these concerns being voiced do not alter the undisputed fact that vaccines are still considered the greatest medical achievement known to man (Allen, A., 2007).

In this time of great uncertainty, especially with an impending threat of bioterrorism, the public and politicians need to understand the danger that thoughtless actions pose to the great immunological commons we have built by decades of vaccinating children. If the vaccination program is to remain successful in eliminating disease, all interested parties need to continue the discourse of vaccines true risks and importantly its benefits. Elected officials must play their part by providing subsidies for vaccines when called for, by providing legal protection from lawsuits for pharmaceutical companies that are doing their honest best to create safe vaccines, and by assuring that those who are accidentally damaged by vaccination will be properly compensated. Only then will vaccination fulfill its promise as our collective commitment to protect children and our population as a whole from infectious disease.

CHAPTER 5

CRITICAL ANALYSIS – THE POLITICAL DEBATE

The purpose of this theoretical inquiry was to elucidate the political, social, and bioethical controversy surrounding the HPV vaccine mandate. The research was inspired by bioethical feminist theory as a theoretical framework. This chapter provides the underlying origins of the political controversy surrounding the HPV vaccine. Jacob Heller, a sociology professor at SUNY Old Westbury, has stated:

Public and heated controversies like those surrounding the HPV vaccine, however, rarely concern the vaccine itself, which typically receives high and hopeful praise once it has passed scientific muster. Instead, conflicts seem to arise around context: the laws regarding vaccine use, the role of corporate lobbying, or the politics of a vaccine designed to protect against a controversial disease. (2008, p. 2)

This chapter focused on the political context of the HPV vaccine controversy in an attempt to understand how we have viewed and understood the role of vaccines in our society.

Let the Debate Commence

Every controversy or debate has two or more points of view. The HPV vaccine is no different; there are several dichotomous distinctions that can be applied to the discussion: political versus social, government versus parents, mandate versus autonomy, rich versus poor, and girls versus boys. Each of these debates are found somewhere within the HPV vaccine literature. The question is, “Why has the HPV vaccine evoked such a storm of controversy?” We have a drug that has been tested safe, effective, and cancer-preventing. So why, since June of 2006, has a shroud of controversy surrounded this vaccine?

According to Anne Donchin and Laura Purdy (1999), bioethical feminist theory “requires us to take nothing for granted, and to question everything” (p. 3). In laying out this debate, both sides are scrutinized for their validity and contribution to the problem at hand – “Should the HPV vaccine be mandated for adolescent girls in order to attend school?” The discussion begins with the rationale for a government mandate of the HPV vaccine. I then discuss what happened when the Texas state government tried to invoke a school-linked mandate for girls. I end the political discussion with the tumultuous story of Merck’s lobbying campaign and heavy marketing of the Gardasil® vaccine.

Reasons for Mandating the HPV Vaccine

Before I explore the reasons for requiring the HPV vaccine for school enrollment it is important to define the term “mandate” as it applies to vaccines. The word mandate comes from the Latin terms *manus*, for hand, and *dare*, for give. A mandate is generally considered to be a command, handed down from a superior to subordinate (Wynia, 2007a). In public health, mandates must fit two criteria. First, opting out of the mandate requires some action beyond simply saying no (Wynia, 2007a). Second, there is an enforcement mechanism that encourages compliance (Wynia, 2007a). Wynia (2007a) has written, “In short, a mandate is not the same as a mere recommendation” (p. 2).

Those that feel that the HPV vaccine should be mandated provide the framework for the political side of the debate. State and federal policy makers, physicians, public health workers, the professional medical and public bureaucracies, and pharmaceutical companies are at the forefront of the political discussion. Jacob Heller (2008) has stated, “Their unanimity about vaccines as beneficent and necessary, coupled with almost no tolerance for dissent about vaccines’ continued use, quickly marginalizes any opposition to vaccines” (p. 23). This section

laid out the reasoning behind the push to mandate the vaccine for adolescent girls.

HPV Vaccine is Effective at Preventing Cervical Cancer

The HPV vaccine represents an important medical accomplishment and a major public health achievement. This vaccine has been tested worldwide with more than 11,000 females between the ages of 9 and 26 years and has been proven to be 100% effective in preventing the four HPV strains that are responsible for 70% of cervical cancers and 90% of genital warts (Vamos, McDermott, & Daley, 2008). In addition to the efficacy, the vaccine has no serious side effects (Krishnan, 2008). A successful vaccination campaign can significantly reduce cervical disease and the burden of invasive procedures, similar to what I experienced, that remove detected precancerous and cancerous lesions of the cervix. By combining routine Pap smear exams and HPV vaccination can drastically reduce cervical disease (Vamos et al., 2008). Pharmaceutical companies have lobbied for the mandating of the HPV vaccine as a way of eradicating cervical cancer (Vamos et al., 2008). This lobbying campaign is misleading because the HPV vaccine protects against the two types of HPV that are responsible for 70% of cervical cancers and not against the types that cause the other 30% of cervical cancers (Krishnan, 2008). A more accurate description would be that the HPV vaccine has the potential to “reduce” the incidence of cervical cancer, but not “eradicate” it. The only clear way of completely eradicating cervical cancer is to make sure that *all* women, in every country, have access to the HPV vaccine, regular Pap smear exams, and follow-up treatments. An unfortunate consequence of the hierarchal structure of any society is that nondominant, powerless groups are, by definition, always marginalized; when persons of these groups become sick, they are doubly marginalized (Holmes, 1999). So is a worldwide campaign to vaccinate and provide Pap smear exams to every woman unattainable?

Vaccinate Before Onset of Sexual Activity

To be most effective in preventing HPV infection, the HPV vaccine will need to be administered before the onset of sexual activity. The vaccine is only effective at preventing *not* treating an HPV infection. Public health experts say that the majority teenagers have sex by the time they finish high school (Hendricks, 2007). The CDC's National Survey of Family Growth, conducted in 2002, shows that 69% of 18- to 19-year-old women, and 64% of men in that age group, have had sex (Hendricks, 2007). Before high school graduation, 14% of sexually active teenagers have had four or more sexual partners (Krishnan, 2008). Targeting adolescent girls before they reach high school is imperative in protecting them from being infected from HPV. Heller (2008) has asserted, "Vaccines by themselves do not prevent disease, they need to be delivered to the susceptible population" (p. 6). A school-linked mandate for HPV would be an effective and efficient way to protect the public from a widespread sexually transmitted disease. The decision to recommend girls between the ages 11 and 12 to receive the vaccine is sound, based upon the science of vaccine development and bolstered by the practicalities of decades of successful vaccination programs. John Niederhuber, Acting Director of the National Cancer Institutes, has stated:

The entire cancer community should be elated and proud. This [HPV vaccine] approval is a watershed moment that highlights the very best of biomedical research: the translation of basic and population science into an intervention that will save hundreds of thousands of lives. (2006, p. 3)

For those parents who do not want to vaccinate their daughters with the HPV vaccine, all 50 states allow them to eschew required vaccines for medical reasons, 48 states allow exemptions for religious beliefs, and 20 states allow exclusion for philosophical reasons (Vamos et al., 2008)

Mandates Force People to Vaccinate

In California, State Assembly member Edward Hernandez has said he will introduce a mandatory measure despite protest from parents. “There’s a great amount of data that shows that people don’t get vaccinations unless they’re mandated. Disease rates don’t start to decline unless it’s mandated”, says Tim Valderrama, Hernandez’s legislative director (cited in Udesky, 2007, p. 979). In the 1970s in Sweden, after reports that pertussis (whooping cough) was no longer a serious disease and was not mandated, vaccine coverage fell from 90% in 1974 to 12% in 1979 (Jacob, Bradley, & Barone, 2005). Disease rates subsequently multiplied 30-fold (Jacob et al., 2005). “Mandates provide a reminder,” said Dr. Louis Cooper, a past president of the American Academy of Pediatrics (cited in Hendricks, 2007, ¶22). Cooper has stated, “When several new vaccines came online in the 1950s and 60s, including polio, measles, mumps and rubella, disease rates did not decline significantly until states started requiring vaccination for school enrollment” (Hendricks, 2007, ¶21). California Assembly woman Sally Lieber also supports the HPV vaccine mandate. She has stated, “Requiring vaccinations against a number of diseases for school enrollment gives us the best chance of controlling preventable diseases in society” (Hendricks, 2007, ¶22). Vaccination is part of our public health and well-being; therefore, it is tied to our public policy. Bradley Monk, a professor of gynecologic oncology at the University of California-Irvine Medical Center, has stated, “Everyday 10 women die of cervical cancer in the United States, and to delay mandating this vaccine because of some uncertainty is like not using penicillin because you’re waiting for a better antibiotic” (Savage, 2007, p. 666).

Adolescence is the Last Opportunity

Another argument for mandating the HPV vaccine is based on the fact that adolescent children and their parents rarely visit family physicians, and would not have the opportunity to

learn about the HPV vaccine. By the time children reach the age of six, all of the major mandatory vaccines have been given. The onset of adolescence often is a time when patients generally are in relatively good health and do not visit their physicians; the majority of adolescent visits are for acute illness and injury (Temte, 2007). Making the HPV vaccine compulsory for adolescent girls, ages 11 and 12, would ensure that they do not miss the best opportunity for receiving the immunization. Daley and McDermott have stated:

This age group is one that is still easily assessable as a cohort to receive widespread protection through school entry programs. Implementing the vaccine in this way guarantees that few adolescents will miss out on this protection, and those who do will benefit from herd immunity. (2007, p. 178)

Cost Effectiveness

As with all medical interventions, the HPV vaccine will come at a cost, although there is little evidence to suggest what that cost will be. One study by Sanders and Tiara (2003) evaluated the cost-effectiveness of giving the HPV vaccine to adolescent girls. The study (target population: all girls living in the United States) concluded that a vaccine that afforded 75% of those immunized would result in a 2.8 days gain in life expectancy. The study hypothesized that if all 12-year-old girls in the U.S. were vaccinated, it would prevent more than 1,300 cervical cancer-related deaths in their lifetimes, similar to the benefits of existing vaccination programs for other diseases (Sanders & Tiara, 2003). Another argument that may be used to justify a mandate for the HPV vaccine is that it is more cost effective to immunize and also cheaper than increasing the frequency of current pap screening tests (Kulasingam & Myers, 2003). Dr. Darrin Strickland, an obstetrician and gynecologist, charges \$135 plus \$90 for lab fees for an annual pap smear, between \$200-\$400 to treat genital warts, between \$700-\$1300 to treat pre-cancerous

cervical lesions, and between \$3500-\$5000 for a hysterectomy due to cervical cancer (personal communication, July 5, 2007). The cost of the hysterectomy does not include pathology costs, radiation or chemotherapy, or treatment by an oncologist. Ralph Insinga (2003) suggests the cost for treating cervical cancer can run as much as \$26,000. The high price tag of the HPV vaccine has been criticized, but in light of the cost of treating genital warts, pre-cancerous lesions, or cervical cancer, the immunization seems to be the cheaper alternative.

About 75% of the 4.7 million abnormal Pap smear screenings that require costly follow-up every year are related to HPV (Merck, 2006). Some authorities have estimated that five billion healthcare dollars are spent in the United States annually on HPV-related disease (Vamos et al., 2008). In addition to expenses, high stress levels associated with repeated testing and ever-present threat of cervical cancer may be eliminated with the HPV vaccine (Biedrzycki, 2007).

Protecting Women Who Do Not Get Annual Exams

Mandating the HPV vaccine would also help protect women who do not receive regular Pap smear screenings. In the U.S., nearly 3,700 women who will die of cervical cancer will have something in common – no screening or no treatment follow-up after screening. These facts speak to access to healthcare, and the conclusion is clear – cervical cancer is a disease of disparity. Women who are able to afford screening by Pap tests and HPV tests will not likely die of the disease (Daley & McDermott, 2007). Rather, the women who lack access to screening and treatment become victims of an otherwise largely preventable disease and cause of death.

Implementation of a mandatory school entry vaccine program guarantees that few adolescents will miss out on this protection, and those who do will benefit from herd immunity. Deborah Arrindell, Vice President of health policy at the American Social Health Association, has stated, “Middle school may be the last public health gate we all walk through together, before children

start dropping out of schools, or getting a crummy job without health insurance, or entering the workforce in general with its fragmented healthcare system” (Houppert, 2007, p. 20).

Arrindell also has contended, “It is vital to mandate the shots. That’s because leaving the shots voluntary means some girls will get them, but a lot won’t. And those who won’t get the shots are those that can’t afford them” (cited in Houppert, 2007, p. 20). If the HPV vaccine is a mandated immunization, then insurance companies are more likely to cover the cost of the injections, and Medicaid will pay for federally funded vaccine programs that offer free vaccines for uninsured children (Houppert, 2007).

Protects Against Genital Warts

Mandating the HPV vaccine not only has the potential of protecting against cervical cancer, it also protects the recipient against the types of HPV that cause 90% of the cases of genital warts (*Harvard Women’s Health Watch*, 2007). There are nearly 1 million cases of genital warts per year in the United States, with both men and women equally affected (Krishnan, 2008). Gardasil® is the only vaccine that is almost 100% effective against HPV types 6 and 11, which account for the majority of genital warts cases (Sharma, 2008). There may also be protection from HPV-induced oral and anal cancers, and recurrent respiratory papillomas (Krishnan, 2008).

Lesson Learned from the Hepatitis B Vaccine

Merck’s prior experience with its hepatitis B virus (HBV) vaccine helped frame its strategy for its HPV vaccine. HBV means inflammation of the liver. HBV can lead to liver failure, jaundice, and in severe cases, death (Link, 2005). Infections with HBV occur by transmission from mother to fetus or from mother to newborn; by blood transfusion; or by contact with sexual secretions, including semen and vaginal secretions (Link, 2005).

Both Merck and federal agencies initially targeted the HBV vaccine for a limited market. ACIP defined the target population for the HBV vaccine narrowly: health care workers who may have contact with blood and other bodily fluids, men who have sex with men, intravenous drug users, prisoners and staff in custodial institutions, and pregnant women in high-risk groups (CDC, 1982). Merck did not suggest that because hepatitis B infections may lead to cirrhosis and liver cancer, the vaccine should be universal. Nor did it challenge the ACIP's presumption that most Americans were at low risk of contracting or dying from HBV-related liver diseases, which in 1982 amounted to approximately 4000 cases (Rothman & Rothman, 2009). Although 800 individuals died annually from hepatitis B-related liver cancer, Merck did not promote the vaccine as an anticancer product (CDC, 1982).

Targeting high-risk groups was not working because the groups where the virus was circulating were hard to reach, and the activities known to spread it were stigmatizing (Allen, A., 2007). So as a result, hepatitis B rates did not decline (Sharfstein, 2000). One reason was an absence of government reimbursement programs. Arthur Allen has stated, "services for junkies and gay men were not a popular line item" (2007, p.311). ACIP, disappointed by the results, in 1991 proposed universal infant vaccination, "before humans who carried it had a chance to make the behavioral choices that spread it" (Allen, A., 2007, p. 311). Nevertheless, use of the HBV vaccine lagged. Link has written:

On its first introduction into the medical community and the general public, there was considerable resistance to the use of the vaccine. The association of hepatitis B with gays, whores, and addicts did not make the vaccine especially popular, and many parents (and doctors) considered themselves and their children at low risk. (2005, p. 115)

A 1992 Merck-funded study reported that two-thirds of pediatricians and one-third of family

physicians thought universal vaccination desirable; however, only half the pediatricians and one-quarter the family physicians made HBV vaccination standard practice (Freed, Bordley, Clark, & Konrad, 1994). Solo practitioners were unwilling to stock the vaccine or await insurance company reimbursement, and many parents objected to adding another injection to the immunization schedule (Freed et al., 1994).

Despite initial doubts, states moved quickly to include HBV vaccination to their mandatory programs (Allen, A., 2007). In 1994, to reduce the number of unvaccinated children, Congress enacted the Vaccines for Children program, covering uninsured and Medicaid-eligible children. Administered by the CDC, the program purchases ACIP-recommended vaccines and supplies them to state and local health departments, who in turn distribute the vaccines to participating clinicians (Orenstein, Douglas, Rodewald, & Hinman, 2005). Once funding was available and universal vaccination recommended, use of the HBV vaccine soared. By 2002, 90% of children younger than 3 years had received it (CDC, 2002). The CDC estimated that in 2002 there were 79,000 new HBV infections, compared to 200,000 to 300,000 in 1982 (CDC, 2002). The vaccine was working. Allen has written:

Part of the credit went to safe-sex behavior in the age of AIDS. But vaccination was having a major impact on infections in babies. There was less hepatitis B among teenagers who'd been vaccinated as children and among adults vaccinated as teenagers. (2007, p. 312)

Interestingly, HBV is the very first vaccine administered to infants. Newborns get the first of three doses before they leave the hospital (CDC, 2009d).

I included the story of HBV because its tumultuous beginning parallels that of the HPV vaccine – both viruses are associated with sexually transmitted diseases; both of the vaccines

faced criticism because contracting the disease was based on a behavioral choice – promiscuous behavior; both require three doses and are two of the most expensive vaccines; both vaccines faced the question if immunity would last into adulthood when people started engaging in the behaviors that put them at risk; both vaccines were developed to target a specific group (HBV – drug abusers, gay men and HPV – sexually inactive girls); and both vaccines have shown great success in reducing the number of infected people for their specific diseases (Allen, A., 2007).

The manufacturing and marketing strategies for the HPV vaccine sought to overcome the obstacles that the HBV had encountered: avoid limiting the vaccine to high-risk populations, promote it for all women, and secure government reimbursement and mandates (Rothman, S. & Rothman, D., 2009). Even in deploying these strategies, Merck encountered problems that it is still trying to overcome. It will be interesting to see if Gardasil® proves to provide lasting immunity will it be mandated for infant girls before they leave the hospital too?

I have discussed the reasoning and logic behind the government’s push to mandate the HPV vaccine. There are certainly valid justifications for a school-linked mandate. Some of these justifications have fueled the public’s skepticism about the government playing “big brother” in terms of dictating health care policy. The next section discusses the reasons that a political debate over the HPV vaccine has ensued.

Causes of the Political Skepticism in Mandating the HPV Vaccine

Success in public health relies on public trust.

-Matthew K. Wynia (2007)

Vaccinations are widely viewed as among the most cost effective and widely used public health interventions. Yet, since Dr. Jenner’s time, vaccination has provoked popular and vocal resistance. Although the population of colonial America generally accepted vaccination, minority

opposition arose in many quarters. Some opponents expressed valid scientific objections about effectiveness; some worried that vaccination transmitted other diseases (like syphilis) or caused harmful effects; and others objected on grounds of religious or philosophical principles. Compulsory vaccination laws were once viewed as an unwarranted governmental interference with one's autonomy and liberty to make his or her personal health care decisions. This latter view is attributable in part to overly assertive public health practices and general public distrust of the public health objectives and policies. A close inspection of the relationship between an aggressive pharmaceutical company and the government gives a citizen good reason to distrust public health policies especially when the pharmaceutical company's marketing practices are reviewed.

Since the approval of Gardasil® in 2006 worldwide sales have been estimated in the billions (Merck, 2008). In the United States, 25% of girls aged 13 to 17 have received at least 1 of 3 recommended doses (CDC, 2008a). To achieve these statistics and profit, the marketing of this vaccine broke with traditional practices. Up until this time, vaccines have been identified by the disease they were preventing (polio, rubella, or measles) or by their creators (Salk, Pasteur, or Sabin) (Allen, A., 2007). This HPV vaccine followed a different model. It was identified by a trade name, Gardasil®, and promoted primarily to “guard” not against HPV viruses or sexually transmitted diseases but against cervical cancer. The marketing campaign that follows, according to Merck's chief executive officer, proceeded “flawlessly” (Herskovits, 2007, p. 60). In 2006, Gardasil® was named the pharmaceutical “brand of the year” for building a market “out of thin air” (Herskovits, 2007, p. 60).

Within weeks following the FDA's approval of Gardasil®, Merck started an unprecedented lobbying blitz, securing 23 states' legislation that would mandate vaccination of

pre-teen girls. Unusually, Merck also targeted adolescents directly through television ads in which free-spirited young girls jump rope, pummel punching bags, or skateboard, declaiming “one less” cervical cancer case, never actually mentioning that HPV is a sexually transmitted disease; while mothers gently admonish, “Gardasil® may not fully protect everyone” and tenderly list the side effects. This all seemed to be working nicely—by the end of 2007 the company had already sold \$1.5 billion worth of the vaccine worldwide (Merck, 2008; see Appendix B). But this marketing sensation soon began to unravel when talk of mandating the vaccine for school entrance started to hit the airwaves.

The debate against mandating Gardasil® comes from many different positions, and arguments are touted by conservative politicians, civil rights groups, evangelical groups, ethical groups, abstinence-only groups, anti-big pharmaceutical groups, and concerned parents. The debate against the HPV vaccine started with the impulsive actions of the governor of Texas. This incident raised many eyebrows and skepticism about the ulterior motives behind the hasty decision to mandate Gardasil® in Texas.

On February 2, 2007, Gov. Rick Perry issued an executive order that required schoolgirls to be immunized against HPV. By employing an executive order, Perry sidestepped opposition in the Legislature from conservatives and parents’ right groups who fear such a requirement would condone premarital sex and interfere with the way Texans raise their children. The executive order would require that girls entering the sixth grade receive Gardasil®. Governor Perry also directed state health officials to make the vaccine available free for girls 9 to 18 who are uninsured or whose insurance does not cover vaccines. In addition, he ordered the Medicaid offer Gardasil® to women ages 19 to 21. Governor Perry stated, “The HPV vaccine provided us with an incredible opportunity to effectively target and prevent cervical cancer” (Peterson, 2007, ¶13).

On April 25th, Texas lawmakers blocked Gov. Perry's effort to make Texas the first state to require sixth-grade girls to be vaccinated with Gardasil[®]. In a 135-to-2 vote the Texas House gave final passage to a Senate bill that bars the state from ordering the shots until at least 2011 (Blumenthal et al., 2007). Even many supporters of the governor resented Mr. Perry's proposal an abuse of executive authority (Blumenthal et al., 2007). Texas Senator Glenn Hegar Jr., who sponsored the bill to overturn the executive order, stated, "There was no public testimony- why were we jumping so fast into a vaccine that was not for a true communicable disease" (Blumenthal et al., 2007).

This incident has not been good for Merck's heavy lobbying and public relations. To compound the problem, Governor Perry has been accused of having political ties to Merck. Before Gov. Perry's executive order in February, Merck was bankrolling efforts to pass state laws across the country mandating Gardasil[®] for girls as young as 11 or 12 years of age. It doubled its lobbying budget in Texas and has funneled money through Women in Government, an advocacy group made up of female state legislators around the country (Peterson, 2007). Gov. Perry's former chief of staff, Mike Toomey, is one of Merck's three lobbyists in Texas. His current chief of staff's mother-in-law, Texas State Representative Dianne White Delisi, is a state director for Women in Government (Peterson, 2007). The governor also received \$6,000 from Merck's political action committee during his re-election campaign.

In late February, Merck decided to drop its legislative campaign and stop pushing for a government mandate due to growing opposition and bad press. Merck's lobbying of Gardasil[®] has been criticized as being more self-serving than promoting women's health (Atkinson, 2007). On January 8, *Business News* cited an analyst with T. Rowe Price who estimated that sales of Merck's HPV vaccine "will peak at \$2 billion per year, but could do as high as \$4 billion if the

states require it” (Jeffrey, 2007, p. 5). *Fortune* magazine reported that Merck’s and GSK’s HPV vaccines are together “projected to spawn \$8-billion-a-year global market by 2010” (Jeffrey, 2007, p. 5). Merck was hoping for a financial boost from Gardasil® because several of its best-selling drugs, like the osteoporosis drug Fosamax®, are coming off patent this year (Sturgeon, 2007). Merck is also in a financial quandary and facing litigation over the withdrawal of the painkiller Vioxx®. There are pending civil lawsuits because the drug was found to increase the chances heart attacks and strokes in patients taking the drug. Vioxx may be responsible for 28,000 deaths (Houppert, 2007).

When it comes to the history of women’s health issues, hindsight has revealed that economic interests and unfounded medical biases have encouraged women to use dangerous and unproven treatments. As a result, drug companies and the medical profession have reaped great financial rewards. Women, however, have suffered and even died as a result. We so easily forget history as it fades into the mists of time.

The history of treating women with unproven and dangerous drugs and procedures is rarely remembered these days. However, the wounds remain. For example, the anti-morning sickness drug, thalidomide, still conjures up images of deformed children (Brown, 2009). The first synthetic estrogen called diethylstilbestrol (DES) used from 1940-1970 to prevent miscarriages was used on 10 million women American women without adequate testing (Titus-Ernstoff et al., 2006). In 1971, the FDA advised physicians to stop prescribing DES because it was linked to a rare vaginal cancer (Titus-Ernstoff et al., 2006). Sadly, it never prevented miscarriage (Titus-Ernstoff et al., 2006). Hormone replacement therapy (HRT), the supposed salvation of menopausal women, is a more recent historical footnote of medical mistakes. We’ll never know how many women died of HRT-induced breast cancer (Fournier, Berrino, & Clavel-

Chapelon, 2008). However, the latest report has shown the incidence of breast cancer has fallen dramatically in the past 4 years. This directly coincides to the decline in HRT use after a major study, the Women's Health Initiative in 2002, found direct correlation with breast cancer and HRT use (Fournier et al., 2008). It seems there is a long history of women becoming unwitting guinea pigs for medical and pharmaceutical interests. The HPV vaccine has only been on the market for 3 years. Obviously there is no long-term data available on the safety and efficacy of the vaccine. Are we adding to the history of using women, or in the case of the HPV vaccine – girls, as guinea pigs all for the right of Merck to tout it's vaccine as the first cancer-preventing immunization?

So as citizens, we must ask ourselves if Merck is more concerned with the health of adolescent girls or the bottom line of its profit margin? I fear the latter may find some bearing. Is Merck turning the cervical cancer-free health of 9 to 26 year olds into a commodity? And what a commodity it is. What consumer would not buy into a product that can improve one's health or future well being? Especially when the illness the drug is able to prevent is cancer. According to the CDC, there were approximately 560,000 cancer deaths in the United States in 2007 (CDC, 2009c). After heart disease, cancer is the second leading cause of death in the United States (CDC, 2009c). Marketing Gardasil[®] as a cancer preventing vaccine was an ingenious strategy designed by Merck. I have always equated the word cancer with terms like death, suffering, radiation, chemotherapy, hair loss, weight loss, and pain. Who would not want to be vaccinated against a disease associated with such devastation and misery? So Merck is making an enormous profit by instilling the fear of getting cervical cancer to perfectly healthy adolescent girls and their parents. According to Krishnan (2008), "It is clear from opinion polls that the vaccine has considerably higher acceptance (63% approval rating) when marketed as a cancer vaccine versus

an STD vaccine (43% approval rating)” (p. 156). Merck’s commercial might as well say, “You could be ‘one less’ to die a horrible death if you are smart and vaccinate yourself with our \$360 drug.” Merck needs to be more upfront with the actual function of Gardasil® – preventing an HPV infection. HPV infection can then lead to cervical dysplasia, a precursor to cervical cancer. Krishnan has written:

Mild dysplasia is more likely to go away without any treatment than severe dysplasias, It is extremely uncommon for cervical dysplasias to progress to cancer if they are properly treated and if women obtain their regular Pap test follow-up exams in a timely fashion. (2008, p. 57)

The high cost of Gardasil® poses a genuine obstacle to patients, physicians, and insurers. According to Marcia Angell (2005), “The United States is the only developed nation that does not regulate drug prices” (p. 219). So Merck can charge whatever price they want for the Gardasil® vaccine in the United States. Merck gained a financial windfall when the CDC voted unanimously to recommend that all girls 11 and 12 years of age receive the vaccine, and had it added to the Vaccines for Children Program, which provides free immunizations to impoverished or underserved children. Since the Vaccines for Children Program is government funded, and the government cannot negotiate drug prices; taxpayers are paying for a very expensive drug, and Merck is cashing in.

Merck has produced a vaccine that is the first of its kind. Gardasil® is a vaccine that has the potential to prevent cancer. This is a scientific breakthrough. It has the ability to save the lives of millions of women. But the cost of the drug is overwhelming. Can’t Merck be satisfied with a billion dollar profit instead of a \$4 billion profit? Does the drug really need to be so expensive? I realize we live in a capitalist system and profit is the incentive that motivates for-

profit corporations like Merck to design pharmaceuticals, satisfy FDA standards, and manufacture and distribute products to the public. Criticism of Merck for seeking a profit or for lobbying to encourage its product's use represents criticism of capitalism itself, not of Merck. So long as Merck has acted within the letter of the law, critics may wish that we had a system better equipped to protect consumers of drugs, to limit corporate lobbying, or to produce safer products. These general criticisms are hardly exclusive to Gardasil®; one could apply them against any product sold by a corporation for profit. In the case of Gardasil®, the bioethics of making billions of dollars profit off of the sexual practices of adolescent girls is unsettling and slightly disturbing. Bioethics feminists Gwen Anderson, Rita Monsen, and Mary Rorty have written, "Because social attitudes, legal remedies, and moral standards typically lag behind scientific and technological developments, it is vital that scientists and technologists consider how their new products might affect the people who use them, negatively as well as positively" (2000, pp. 38-39).

Does Merck really need to charge \$360 per dose to earn back what it has spent on developing it? The company estimates its net income for 2006 at nearly \$4.5 billion. If it sold Gardasil® for 1/10th its current price, assuming the number of units sold stays relatively steady, the company would have \$36.5 million in sales each quarter, or \$146 million each year, from that product alone. A few more months, and it could recoup its development cost, and start making up for the funds wasted on researching vaccines that didn't make it to market.

Merck's marketing campaign has been hypocritical because it has argued to legislators that Gardasil® is an essential tool for public health, and then raised the price to a level that most women can't afford, especially those outside the United States who are hit the hardest by cervical cancer. In the first year Gardasil® could be marketed in the US, Merck has spent approximately

\$70 million on advertisements and lobbying campaigns touting the vaccine (Edwards, 2007). They have used celebrity endorsers like MTV's *TRL*, Susie Castillo and have sent out 82,000 bead kits that can be assembled into "Make the connection" cervical cancer awareness bracelets (Edwards, 2007). If the company can afford to spend huge amounts of money convincing legislators the vaccine is something every woman deserves, it can afford to take its own advice, and reduce the price. It could be said the Merck is guilty of "The Tragedy of the Commons." According to Garrett Hardin, "All commons dependent upon finite material substances, such as land, would look only to his own interest and not to the community needs" (Waldby & Mitchell, 2006, p. 138). In this case Merck is more interested in the profit that Gardasil® will bring it, than in the stemming of the worldwide epidemic of cervical cancer.

Summary

The HPV vaccine is a significant biomedical and public health achievement. Medical research has established that HPV is responsible for causing most of the cases of cervical cancer (Krishnan, 2008). Immunizing adolescent girls with the HPV vaccine is cost effective and significantly saves health care dollars otherwise spent on treatment and diagnosis of this sexually transmitted disease. Mandating the vaccine could ensure widespread protection and distribute the immunization to children regardless of race, ethnicity, or socioeconomic status. History has proven that mandates force people to vaccinate. If the public health goal is to ensure that every adolescent girl is protected against cervical cancer, then mandating the HPV vaccine would be appropriate.

Skepticism towards politicians and state governments who wanted to quickly mandate the vaccine arose because there was not a consensus among all parties involved. Many state legislators backed down after parents, advocacy groups, and public-health officials protested the

proposed mandates. Many blamed Merck's heavy lobbying efforts for the push to mandate the vaccine, while others believe overeager pro-vaccine advocacy groups, like Every Child By Two, were to blame. The politics surrounding the HPV vaccine has brought it into the national limelight. Alan Hinman, a senior public health scientist at the Taskforce for Child Survival and Development, has asserted, "This is a marvelous vaccine. And instead of talking about that and how we can try to bring it to everyone who should get it, the discussion has shifted to be about the controversy of mandating vaccines" (Savage, 2007, p. 665). In the U.S., for all the childhood diseases for which there are vaccines and mandates, disparities, for all intents and purposes, have been eliminated. The mandated vaccination program that is linked to school entrance is the most color-blind health-delivery program that we have. If HPV were added to this program, all girls no matter race, color, or socioeconomic status would be afforded the protection from the most prevalent STD in the world.

The next chapter discussed the social debate surrounding the HPV vaccine and the push to mandate it. This debate focuses on parental concerns about safety, longevity, and the right to make medical decisions for their children without being forced to by the government. The arguments found within the social debate do not support a government mandate and tend to focus on parental autonomy.

CHAPTER 6

CRITICAL ANALYSIS – THE SOCIAL DEBATE

For the first time in the history of medicine we have a medical breakthrough that has the potential of preventing certain cancers in women. This fact has been overshadowed by the impassioned debate between the government wanting to mandate the HPV vaccine and parents wanting a choice about making medical decisions for their daughters. In order to have a successful vaccination campaign there must be a consensus between parents, physicians, and policy makers about the right course of action to take concerning the health decisions of children. The social debate presents the reasons not to mandate the HPV vaccine. Those who have opposed mandating vaccination against HPV as a condition for school entry generally open the debate with two fundamental questions. First, how can the government interfere in the medical decisions parents make for their children by compelling immunizations for school entry? Second, how can the HPV vaccine be a good candidate for school mandates when HPV infection is transmitted only through intimate contact, not through casual encounters, as with other diseases that are preventable with vaccines? A portion of the rebuttal to the political debate also consists of parents, church leaders, and abstinence-only advocates who believe vaccinating adolescent girls against a sexually transmitted disease will lead to a promiscuous lifestyle.

Reasons Against an HPV Vaccine Mandate

Having laid out the reasoning behind a government mandate of the HPV vaccine in the previous chapter, I have turned the debate to the other side. The FDA approval of a vaccine against cancer-causing HPV types is a significant public health advancement. In the face of this advancement, some may say that opposing a government mandate is foolhardy, if not heretical; but I am aiming to expose and provide transparency of the political debate as well as the social

concerns that have ensued over the last 3 years. Earlier in my inquiry I had posed the question, “If the HPV vaccine has the potential to prevent certain types of cervical cancer, then why not mandate the immunization for adolescent girls?” Clearly, we have valid reasons for a government mandate – proven efficacy, best way to protect the public from the spread of HPV, and increases likelihood that insurance companies will cover the drug. But there are also valid reasons not to mandate the vaccine for adolescent girls. Presenting both sides of the debate allows us to step back and focus on the best way to first, stop the spread of HPV and second, find a non-controversial place for the HPV vaccine in our society as well as developing countries who need it most.

Let the Debate Continue – Long-Term Safety and Effectiveness of the Vaccine is Unknown

First and foremost the safety of our children is the most important issue in this whole debate. Heller has asserted:

Americans’ skepticism about vaccination safety has varied over time, depending on the particular disease, whether there is an ongoing epidemic (or a likely threat of one), political affiliation, attitudes about the appropriate role of government, religious beliefs, and the reputation of the health professions. (2008, p. 104)

Although the aim of clinical trials is to generate safety and effectiveness data that can be presented to the general population, it is widely understood that such trials cannot reveal all possible adverse events related to a product. Marcia Angell (2005) has written:

Even large, well-designed Phase III trials may not reveal side effects if they are very rare or no one thought to look for them. They may also miss other effects that show up only in patients different from those previously studied. (p. 162)

For this reason, post-market adverse event reporting is required for all manufacturers of FDA-approved products, and post-market surveillance (also called phase IV clinical trials) may be required in certain circumstances. There have been numerous examples in recent years in which unforeseen adverse reactions following product approval led manufacturers to withdraw their product from the market. Some examples are drugs like Rotashield, a vaccine to prevent rotavirus gastroenteritis, that was found to cause intussusceptions; and Vioxx, a drug used to reduce arthritic pain, that was found to increase the risk of having a heart attack.

In the case of the HPV vaccine, short-term clinical trials with thousands of young women did not reveal serious adverse side effects. As of June 30, 2008, the most recent date for which the CDC has made data available, over 16 million doses of Gardasil[®] have been distributed in the US and there have been 9,749 VAERS (Vaccine Adverse Event Reporting System) reports of adverse events following vaccination (CDC, 2008c). Of these, 95% were classified as non-serious, and 6% as serious events (CDC, 2008c). The serious events range from unconfirmed reports of Guillain-Barre syndrome (GBS), a neurological illness resulting in muscle weakness and sometimes paralysis, to bronchospasm, gastroenteritis, headache with hypertension, joint movement impairment near injection site, and vaginal hemorrhage (Javitt et al., 2008). The adverse events reported since the vaccine's approval are, at the very least, a sobering reminder that rare adverse events may surface as the vaccine is administered to millions of girls and young women. With this being said, we must remember that vaccines aim to protect the entire target population. There must be a one-size-fits-all drug that works across all races, ages, genetic backgrounds, and individual medical histories. Heller has written, "Vaccines are an interesting exception [to drug classifications]: they deal not with individual patients who have specific complaints, but with statistical rates of immunity in populations, in hope of avoiding the need for

treatment (2008, p. 25). Vaccines remain one of the safest interventions with very small risks to the population as a whole (Allen, A., 2007).

The duration or long-term effectiveness of an HPV vaccine-induced immunity is unclear. The average follow-up period for Gardasil® during clinical trials was 15 months after the third dose of the vaccine (Javitt et al., 2008). There were three phase II trials performed that included follow-up for 4 to 5 years after the third injection was given. The studies found no evidence of waning immunity or decreased efficacy for the prevention of an infection (FUTURE II Study Group, 2007). The vaccine seems to be safe for up to 5 years after it is given, beyond that is unknown (*Harvard Women's Health Watch*, 2007). If ACIP is recommending the vaccine for 11- and 12-year old girls then by the time they are 17 or 18 they may need a booster shot. If a 17- or 18-year old girl, who in all likelihood, is sexually active, misses the booster shot she could be at risk of acquiring an HPV infection due to waning immunity. Not only has she wasted at least \$360, but also her preventive vaccine has failed her miserably.

The minimum protective antibody threshold for disease protection is currently unknown (Cutts et al., 2007). Follow-up studies are planned to determine antibody levels, side effects, and long term effectiveness among women through at least 14 years after dose three is given (Cutts et al., 2007).

The current Advisory Committee on Immunization Practices (ACIP) recommendation is based on assumptions about duration of immunity and age of the onset of the first sexual experience (Javitt et al., 2008). As the vaccine is used for a longer time period and long-term data is collected, it may turn out that the vaccine schedule will need to be revamped or a booster shot will be required. Another safety concern that is currently lacking data is the effect on co-

administration of other vaccines. It is unknown whether Gardasil® may be administered with other vaccines.

At present questions remain about the vaccine's safety and the duration of its immunity, which call into question the judgment of mandating this immunization for school entrance. Girls receiving the vaccine face some risk of potential adverse events as well as the risk that the vaccine will not be completely protective over the long term. Physicians have a responsibility to inform parents of the risks of the vaccine and decide together if the benefits of the vaccine outweigh the risks.

Constitutional Justifications for Mandated Vaccine are Not Met

HPV and its vaccine are different in several respects from the immunizations that first led to state-mandated vaccination. Going back to the opening sentence of my dissertation, it was 1855 when compulsory vaccination laws originated. They were motivated by fears of the centuries-old pandemic of smallpox and the advent of the vaccine developed by Edward Jenner in 1796. By the 1900s, the vast majority of states had enacted compulsory smallpox vaccination laws (Bazin, 2000). While such laws were not immediately tied to school attendance, the coincidental rise of smallpox outbreaks, growth in the number of public schools, and compulsory school attendance laws provided a rationale for compulsory vaccination to prevent the spread of smallpox among school children as well as a means to enforce the requirement by barring unvaccinated children from school (Duffy, 1978). In 1827, Boston became the first city to require proof of immunization with the smallpox vaccine before a child could enter public school (Gostin, 2005). Similar laws were enacted by several states during the latter half of the 19th century (Gostin, 2005).

As discussed earlier, the theory of herd immunity was the motivating force behind mass immunization programs. Herd immunity suggests that, in diseases passed from person to person, it is difficult to maintain a succession of infection when substantial numbers of the population are immune. With the increase in number of immune individuals present in the population, the lower the likelihood that a vulnerable person will come into contact with an infected individual. As vaccination rates increase, protection from the disease also increases until the infection is eliminated. This is how smallpox has been completely eradicated from the human population (Bazin, 2000).

As more governing states had begun to mandate vaccination, courts were called on to give a ruling on the constitutionality of mandatory vaccination programs (Gostin, 2005). In 1905, The Supreme Court decided the influential case, *Jacobson v. Massachusetts*, in which it upheld a population-wide smallpox vaccination ordinance challenged by Reverend Henning Jacobson who refused to be vaccinated and was fined \$5 (Gostin, 2005). Rev. Jacobson argued that a compulsory vaccination law was “hostile to the inherent right of every freeman to care for his own body and health in such a way as to him seems best” (Javitt et al., 2008, p.388). The Court disagreed with Jacobson and upheld the state’s right to mandate the smallpox vaccine. The Court adopted a narrower view of individual liberty and emphasized the duties that citizens have towards each other and to the society as a whole (Gostin 2005). According to the Court, the:

liberty secured by the Constitution of the United States...does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. (*Jacobson v. Massachusetts*, 1905, p. 197)

With respect to compulsory vaccination, the Court stated, “upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members” (*Jacobson v. Massachusetts*, 1905, p. 197). In the court’s opinion, compulsory vaccination was consistent with a state’s traditional police powers – its power to regulate matters affecting the health, safety, and general welfare of the public (Gostin, 2005).

In reaching its decision, the Court was influenced both by the considerable harm posed by smallpox – using the words “epidemic” and “danger” repeatedly – as well as the available scientific evidence demonstrating the efficacy of the vaccine (Javitt et al. 2008). However, the Court also emphasized that its ruling was valid only to the case before it, and articulated four principles that must be adhered to for such an exercise of police powers to be constitutional (Javitt et al., 2008). The principles are: (a) there must be a public health necessity; (b) there must be a reasonable relationship between the intervention and the public health objective; (c) the intervention may not be arbitrary or oppressive; and (d) the intervention should not pose a health risk to its subject (Javitt et al., 2008).

The smallpox rulings of the nineteenth century helped lay the foundation for modern immunization laws (Gostin, 2005). In 1977, the federal government launched the Childhood Immunization Initiative, which stressed the importance of strict enforcement of school immunization laws (Hinman, Orenstein, Williamson, & Darrington, 2002). Currently, all states have mandated vaccination as a condition for school entry, and in deciding whether to mandate certain vaccines are guided by ACIP recommendations (Allen, A., 2007). At present, ACIP has recommended vaccination for diphtheria, tetanus, and acellular pertussis (DTaP), hepatitis B, polio, measles, mumps, and rubella (MMR), varicella, influenza, rotavirus, haemophilus

influenza B (HiB), pneumococcus, hepatitis A, meningococcus, and most recently HPV (CDC, 2009d). An interesting point that bioethical feminists have argued is the role of the medical field on the social authority of our society. Helen Holmes has written, “Medicine’s social authority ensues because society automatically accepts medicine’s pronouncements, descriptions that then determine how social institutions (such as courts, schools, insurance companies) control our lives” (1999, p. 47). ACIP decides which vaccines should be administered to children, places them on a *recommended* immunization list, then the state governments, using the *recommendation* of ACIP, mandates them for school entrance. We have gone from a recommendation to a mandate based on the pronouncement of science, which then establishes the social authority of ACIP.

HPV is different from the vaccines that have previously been mandated by the states. All of the previous vaccines, with the exception of tetanus, fit comfortably within the “public health necessity” principle articulated within *Jacobson* in that the diseases they prevent are highly contagious and are associated with significant morbidity and mortality occurring shortly after exposure.

Jacobson’s “reasonable relationship” principle is also clearly met by vaccine mandates for the other ACIP recommended vaccines. School-aged children are most at risk while in school because they are more likely to be in close proximity to each other in that setting. All children who attend school are equally at risk of both transmitting and contracting the diseases. Thus, a clear relationship exists between conditioning school attendance on vaccination and the avoidance of the spread of infectious diseases within the school environment.

HPV, in contrast, does not satisfy these two principles. HPV infection presents no public health necessity. While non-sexual transmission routes are theoretically possible, they are highly

unlikely (Krishnan, 2008). Like other sexually transmitted diseases which primarily affect adults, it is not immediately life threatening; as such, cervical cancer, if developed, will not manifest for years. Furthermore, the majority of those exposed will not go on to develop cervical cancer (Krishnan, 2008). Thus, conditioning school attendance on HPV vaccination serves only to coerce compliance in the absence of a public health emergency.

The relationship between the government's objective of preventing cervical cancer in women and the means to achieve it – that is, vaccination of all girls as a condition of school attendance – lacks sufficient rationality. First, given that HPV is transmitted through sexual contact, exposure to HPV is not directly related to school attendance. Second, not all children who attend school are at equal risk of exposure to or transmission of the virus. Those who abstain from sexual conduct are not at risk for transmitting or contracting the virus.

The public health objective that proponents of mandatory HPV vaccination seek to achieve is compelling and backed by scientific findings. These findings recommend vaccinating girls before the onset of sexual activity provides the best protection against an adult onset sexually transmitted disease. This opportunity is lost once sexual activity begins and exposure to HPV occurs (Krishnan, 2008). However, the HPV vaccination may be both medically justified and a prudent public health measure, but that is insufficient basis for the state to compel children, specifically girls, to receive the vaccine as a condition of school attendance.

Risking a Public Backlash

Childhood vaccination rates in the United States are very high; more than half of the states report meeting the Department of Health and Human Services (HHS) Healthy People 2010 initiative's goal of $\geq 95\%$ vaccination coverage for childhood vaccination (Stanwyck, Davila, Lyons, & Knighton, 2009). However, from its inception, state mandated vaccination has been

accompanied by a small but vocal anti-vaccination movement. Opposition has historically been “fueled by general distrust of government, a rugged sense of individualism, and concerns about the efficacy and safety of vaccines” (Gullion, J., Henry, & Gullion, G., 2008). In recent years, vaccination programs have been a “victim of their tremendous success, as dreaded diseases such as measles and polio have largely disappeared in the United States, taking with them the fear that motivated past generations” (Javitt et al., 2008, p. 390). Activities of today’s antivaccinationists seem to be having an impact. In recent years, the rates of parents claiming nonmedical vaccination exemptions for their children have increased (Gullion, J. et al., 2008).

One reason for this increase in anti-vaccination rhetoric is the number of mandated vaccines we give our children. Vaccine-safety advocates are concerned about adding more injections to the already full schedule of childhood immunizations. The CDC currently recommends children receive 48 doses of 14 vaccines by age six and 53 doses of 15 vaccines by age 12 (CDC, 2009d). With the addition of the HPV vaccine, girls would receive 56 doses of 16 vaccines by age 12 (CDC, 2009d; see Appendix C and D).

The rash decision of state legislators to mandate HPV had led to significant public concern that the government is overreaching its police power authority. As one conservative columnist has written, “[F]or the government to mandate the expensive vaccine for children would be for Big Brother to reach past the parents and into the home” (Hart, 2007, p. B6). Some might dismiss this statement claiming moral politics, but trivializing this concern is inappropriate because sexual behavior is involved in transmission and not all children are at equal risk of contracting the disease (Javitt et al., 2008). Thus, it is reasonable to take the parent’s judgment into account when considering his or her child’s specific risk of contracting HPV and weigh that against the risk of vaccination.

Javitt et al. (2008) have written, “To remove parental autonomy in this case [HPV vaccination] is not warranted and also risks parental rejection of the vaccine because it is perceived as coercive” (p. 390). In contrast, educating the public about the value of the vaccine may be highly effective without risking public backlash. According to one poll, 61% of parents with daughters under 18 prefer vaccination, 72 % would support the inclusion of information about the vaccine in school health classes, and just 45 % agreed that the vaccine should be included as part of the vaccination routine for all children and adolescents (Cummings, 2006).

Parental attitudes are crucial to the acceptance of the HPV vaccine (Krishnan, 2008). According to Waller et al. (2003) overall parental knowledge about HPV infections and their relationship to cervical cancer and genital warts is minimal. A study in the *Cancer Epidemiology Biomarkers and Prevention* journal showed that only 40% of women had never heard of HPV, and less than 50% of those women knew that it causes cervical cancer (Savage, 2007). A study by Brewer and Fazekas (2007) found that only 59% of women knew the purpose of having an annual Pap smear.

Parents’ acceptance is usually influenced by the attitudes of their peers and their health-care providers (Krishnan, 2008). Their acceptance is also high when they perceive the disease’s consequence to be serious, and when they have had some personal experience with the disease themselves (Dempsey, Zimet, Davis, & Koutsky, 2006). I can attest to this fact seeing that I have had some experience with the disease that the HPV vaccine prevents. I have two young daughters who I plan to have vaccinated if the efficacy and safety data remains favorable. In contrast, acceptance rates are low with parents that lack information or have little concern about the HPV disease (Krishnan, 2008). Additionally, “parents’ acceptance is low among those who feel that their child’s personality, behavioral characteristics, and emotional immaturity place

them at minimal risk for initiating sexual activity and acquiring an STD in the near future” (Krishnan, 2008, p. 153).

Blumenthal, Hetman, Trocola, and Slomovitz (2008) have asserted that among parents who were both for and against the vaccine, many of them said that they would be more willing to accept the vaccine closer to the time of their child’s sexual debut, rather than at age 11 or 12, which parents believe to be far before the time that their child would consider having sex. Krishnan (2008) has written, “Parents’ knowledge of their adolescent child’s sexual activity status is often inaccurate, and so relying on this cue to take action to vaccinate may be unrealistic and unreliable in relation to the child’s need for protection” (p. 153). In a study by researchers at the University of Minnesota Adolescent Health Center, half of American mothers of sexually active teens were unaware of the activity, believing them to be virgins (Moms unaware of teens’ sexual activity, 2002). The key to success for any public health measure is to gain community support and acceptance. If parents and adolescences feel they have been well versed about HPV and feel they have a choice about the vaccination then we can hopefully see a decline in the incidences of HPV.

Unresolved Economic Concerns

Mandated HPV vaccination may have negative unintended economic consequences for both state and health departments and the federal government, and these consequences should be thoroughly considered before HPV vaccination is mandated. In recent years, state health departments have found themselves increasingly financially strapped by the rising number of mandated vaccines. Some states that once provided free vaccines to all children have abandoned the practice due to rising costs. For example, Alaska will no longer offer all vaccinations free to all Alaska schoolchildren; it is cutting funding for the HPV vaccine and the meningococcal

vaccine (Bryson, 2008). Laurel Wood, manager of the Alaska Immunization Program, has stated, “Federal funding of the state’s universal immunization program has failed to keep pace with the increasing cost and rising number of recommended vaccines” (Bryson, 2008, ¶4). Adding HPV could drive more states to abandon funding for other vaccinations and could divert funding from other important public health measures. In the case of Alaska, Wood has stated, “The cost of the HPV vaccine is the budget-buster” (Bryson, 2008, ¶15). At the federal level, spending by the federal Vaccines for Children program, which pays for immunizations for Medicaid children and some others, has grown to \$2.5 billion, up from \$500 million in 2000 (Pollack, 2007). It is estimated that state and federal governments pay for vaccines for roughly 55% of all U.S. children, mainly comprised of the poor (Pollack, 2007). Thus, before HPV vaccination is mandated, a thorough consideration of its economic consequences for existing vaccine programs and other non-vaccine programs should be undertaken.

Not on Equal Ground with Other Vaccines

Childhood immunizations, such as measles, chicken pox, and polio are mandatory for school aged children and are required because of their highly contagious nature, especially in a school setting where people congregate in large numbers and are confined to small spaces (Allen, A., 2007). The majority of mandated vaccines protect against highly contagious diseases that cause significant morbidity and mortality and threaten both the individual and the community (Allen, A., 2007). It is not clear that HPV and the risk of cervical cancer to women fall into that category. Therefore, the question is whether there is justification for mandating parents to vaccinate their daughters against a sexually transmitted virus, one that only can be transmitted through sexual behavior that some people view as being irresponsible. Moreover, the vaccine only protects against high-risk HPV types for 70% of cervical cancers (Krishnan, 2008).

This incomplete protection does not reduce susceptibility to the other HPV types that cause the remaining 30% of cervical cancers and will still require females to undergo yearly cervical cancer screenings and to practice other preventive measures of reducing STD exposure (Krishnan, 2008). Regular Pap smears have made cervical cancer a treatable disease, significantly reducing the number of cervical cancer deaths (Krishnan, 2008). HPV can be contained through behavioral changes and is not communicable through ordinary daily interactions. Therefore, mandating the HPV vaccine for girls of school age is an unnecessary action in response to a promiscuous but preventable behavior. People adopting this position view a state mandated policy that places HPV on the same playing field with other infectious disease-related vaccines as unwarranted.

Giving Children a “License” for Sex

This rationale against mandating the HPV vaccine is the argument that I believe has the least validity and is completely irrational. I have a hard time understanding why parents actually believe that inoculating their daughters with a vaccine that prevents a sexually transmitted disease will cause her to become promiscuous. Having recently taken a Theories of Adolescence course for my doctoral work, I understand that adolescence is a time when constant hormonal surges and bodily transformations are occurring. Teens are more likely to take risks and challenge their parents’ authority and moral values (Krishnan, 2008). Vamos et al. (2008) write, “Adolescence is a time where concrete and short-term cognitions are common and abstract and long-term consequences are only just beginning to develop” (p. 303). Even with this being said, do these hysterical parents, yes I have said it – hysterical – believe a vaccine will lead to sex have so little trust and confidence in their daughters that they will put her health at risk? Sharpe (2007) has stated, “Routine technological interventions intended to protect and save human lives

rapidly dehumanize us as patients” (p. 44). The HPV vaccine was developed to protect us against an HPV infection with hopes of saving many lives in the process. But the notion of not vaccinating because it could promote sex is extremely dehumanizing to adolescent girls. It is inevitable that whether she has sex at 16 or sex at 26, she is going to have sex (unless she joins a convent). Instead of automatically assuming that parents are giving their daughters permission to have “vaccinated sex,” why not look at this technological advancement as a way of protecting them from a possible life threatening disease. Furthermore, such a policy recklessly discounts the priority of preserving women’s health and inappropriately treats a potentially deadly disease as something of an affordable cost or a legitimate punishment for women’s unsanctioned sex. Finally, the “leads to promiscuity” attitude purposefully retains the high-risk types of HPV in the population. If enough girls, and eventually boys, were vaccinated then there would be a reduction in types 16 and 18 HPV. The question would become: would one of the other “high-risk” types of HPV fill the niche left by types 16 and 18? Hopefully by then the vaccine could be extended to cover all high-risk types of HPV.

I should not be so hard on conservative parents, I used to be one of them; but as I have moved through the process of researching and writing this inquiry I have changed my beliefs about abstinence-only education – it is unrealistic in today’s society of all-persuasive, sexually suggestive media.

Conservative parents are not the only ones framing the “license for sex” argument. Abstinence only groups, religious organizations, and compassionate conservatives are also worried that a mandatory HPV vaccination order will promote premarital sex and give children tacit permission to engage in risky sexual behavior. In place of a vaccination program, these groups advocate abstinence education and better communication between parents and children to

foster family values that prohibit premarital sexual relationships. I agree that communication between parents and children in regards to sex is paramount to properly educating adolescence on safe sexual practices. I disagree with the abstinence only approach to teaching our youth about sex.

Studies have shown that abstinence only programs do not reduce the sexual activity of teenagers (Charo, 2007). Promoters that encourage abstinence-only and limit sexual and reproductive health education have touted that these programs are the cause of a reduction in teen pregnancy (Thomas, 2008). But a reduction in teen pregnancy does not mean teens are remaining abstinent. Research from the Vital and Health Statistics of the CDC report that 30% of females aged 15 to 17 and more than 70% of females aged 18 to 19 engage in sexual intercourse and for males 31.6% aged 15-17 and 64.7% aged 18-19 engage in sexual intercourse (CDC, 2009e).

Despite the recent decline, the U.S. teen pregnancy rate still remains very high, even with abstinence-only programs taught in many schools (Kirby, 2007). In 2002, among all females aged 15-19, about 75 per 1,000 became pregnant (Guttmacher Institute, 2006). The rates are higher for African-Americans (134 per 1,000) and Hispanics (132 per 1,000) than non-Hispanic Whites (48 per 1,000; Guttmacher Institute, 2006). Teen sexually activity also leads to high rates of STDs (Kirby, 2007). Hillard Weinstock, Stuart Berman, and Willard Cates have written, “Although young people aged 15-24 represent 25% of the sexually active population, they account for about half of all new cases of STDs” (2004, p.6). Again, STD rates for minorities are typically much higher than the rates for Whites (Kirby, 2007). These higher rates reflect greater poverty, less access to health services, and larger numbers of sexual partners (Kirby 2007).

A study was performed that evaluated the impact of five abstinence-until-marriage programs that were implemented in schools; in health, family planning and STD clinics; and in community organizations working with youth (Trenholm, Devaney, Fortson, Quay, Wheeler, & Clark, 2007). They employed rigorous experimental design and analysis and tracked youths for 4 to 6 years. They concluded that well-designed intensive abstinence-until-marriage programs are not effective in changing sexual behavior (Trenholm et al., 2007). They also found that there was little evidence that any particular abstinence program delays the initiation of sex and did not reduce the risk of getting pregnant or contracting an STD (Trenholm et al., 2007).

In another study, a comprehensive-based sex program was also evaluated for its impact of the sexual behavior of teens (Coyle, Kirby, Marin, Gomez, & Gregorich, 2004). Comprehensive programs may emphasize abstinence but also support condom or contraceptive use. The focus of most comprehensive programs is to prevent pregnancy and STDs (Kirby, 2007). The study showed that there was a decrease in sexual activity, reduction in the number of cases of unprotected sex, and a delay in sexual initiation (Coyle et al., 2004). We know teens are having sex, not all of them, but a good portion. Abstinence-only programs are not as effective as comprehensive based programs at educating our youth about sex, pregnancy, and STDs. Parents, educators, abstinence-only groups, and the federal government (who spends \$170 million each year on abstinence-only programs) (Robin, 2006) need to be more realistic and open-minded about what should be presented to our adolescent children when it comes to discussing taboo issues like sex, teen pregnancy, and STDs.

With this data in hand, what can we conclude about the notion that administering the HPV vaccine will increase teenage promiscuity? Will a teenage girl who just received the Gardasil® vaccine become more promiscuous because she thinks she is safe from contracting

HPV? Does she believe that she has a “license” for sex? Does she believe that her parents condone sex before marriage since they vaccinated her against an STD? The answers to these questions can be answered by looking at what factors influence teenage girls to initiate sexual behavior.

Sexuality is one of the most salient and psychological issues for adolescents and young adults (Katchadourin, 1990). A number of studies have linked early initiation of sexual activity in adolescents with poor-quality relations between mother and fathers, and between adolescents and their parents (McLaughlin, Chen, Greenberger, and Biermeier, 1997). For example, Newcomer and Udry (1987) found that parental characteristics such as marital disruption and lack of parental control were associated with adolescent sexual activity; and along the same lines, Inazu and Fox (1980) found that Caucasian and African-American girls (14-16) who reported high-quality relationships with their mothers were much less likely to have become sexually active. Whitebeck, Hoyt, Miller, and Kao’s (1992) study of 13- to 18-year olds suggested that adolescent daughter’s level of depressed mood was a possible mechanism by which the quality of the mother-daughter relationship might influence the timing of first sexual intercourse; girls who had more supportive mothers were less depressed, and in turn were less likely to engage in first intercourse before age 18. Furthermore, adolescents’ sexual activity is related to peer factors such as association with sexually active peers, peer endorsement of sexual activity, and peer rejection during childhood (Benda & DiBlaso, 1994). An interesting study by Jessor, S., Costa, Jessor, L., and Donovan (1983) found that individuals who remained virgins into young adulthood had been adolescents who, in an earlier assessment, reported themselves to be less physically attractive and less successful at forming romantic relationships. Each of these

studies indicate that a girl's decision to become sexually active is much more complicated than deciding to have sex because she received a vaccine for an STD.

Even though the majority of Americans have sex before they are married, there is a small percentage (less than 10%) who abstain (Finer, 2007). Even young women who have abstained from sex until marriage have contracted HPV from their husbands and faced the difficult task of defeating cervical cancer (Gilman, M., Gilman, S., & Johns, 2009). Unfortunately, a woman's sexually healthy premarital lifestyle does not protect her from contracting HPV – even faithful, monogamous women can get infected with HPV. She has no control over her future husband's premarital lifestyle. With this being said, abstinence does not protect against an HPV infection unless *both* the husband and wife are virgins when they marry.

With the introduction of the HPV vaccine for 11-and 12-year olds, a window of opportunity has been opened for parents and health-care providers to give some anticipatory behavioral guidance to adolescents. Krishnan has stated, “The HPV vaccine cannot, will not, and should not replace proper parenting and discussions with your children about sexuality” (2008, p. 153).

Summary

Based on the current scientific evidence, vaccinating girls against HPV before they are sexually active appears to provide significant protection against cervical cancer. The vaccine thus represents a significant public health advance. Nevertheless, mandating HPV vaccination at the present time would be premature and ill advised. The vaccine is relatively new, and long-term safety and effectiveness in the general population is unknown. Vaccination outcomes of those voluntarily vaccinated should be followed for several years before mandates are imposed. Additionally, the HPV vaccine does not represent a public health necessity of the type that has

justified previous vaccine mandates. State mandates could therefore lead to a public backlash that will undermine both HPV vaccination efforts and existing vaccination programs.

Furthermore, the economic consequence of mandating HPV are significant and could have a negative impact on financial support for other vaccines as well as other public health programs. These consequences should be considered before HPV is mandated. Additionally, HPV cannot be contracted through a cough or sneeze. It is a sexually transmitted disease that is contracted through, for the most part, a behavioral decision. Placing the HPV vaccine on the mandated vaccines list with polio, measles, and chicken pox is premature. Finally, using the illogical position that vaccinating adolescent girls will cause them to be more promiscuous is unfounded. Studies have shown that teenagers with involved parents are more likely to delay the initiation of sexual activity than those teenagers who do not have any parental guidance on sex-related topics such as abstinence and on the psychological and physiological side effects of sexual activity (Krishnan, 2008).

The next chapter has taken the debate out of the political and social realm and into the bioethical sphere. Chapter 7 focused on the ethical and moral ramifications that the HPV vaccine incites within the bioethical feminist literature.

CHAPTER 7

CRITICAL ANALYSIS – THE ETHICAL DEBATE

When I first heard of the HPV vaccine and what it prevents I was excited for all women; I was excited that science and medicine has now focused on an important woman's health issue. We finally have a vaccine that prevents 70% of the cases of cervical cancer and 90% of the cases of genital warts. Women have a weapon against the second leading cause of cancer death in developed countries and the first leading cause of cancer death in developing countries. However, an investigation into the role of the HPV vaccine in our society raises some bioethical feminist issues that must be discussed in order to present a transparent picture of the immunization and its significance for women. Bioethical feminist theory "sees oppression based on gender as a serious wrong and critically investigates the workings of power and gender (Wolf, 1996, p. 8). The HPV vaccine is a medicine that is used to remedy a disease that often affects those that are marginalized – women and minorities. With this being said, the HPV vaccine is the most expensive vaccine on the market. So how are the women who need the drug the most going to afford it? Furthermore, this drug could make a huge impact in developing countries. How will women in those countries access this vaccine? This chapter investigated how this vaccine marginalizes women and what can be done about it.

HPV-induced Cervical Cancer is a Health Inequity Issue

Ninety-nine percent of cervical cancer in women can be directly attributed to HPV; the cause of the other 1% is unknown (Walboomers et al., 1999). Cervical cancer is a disease of social inequality. Women with access to effective screening and treatment rarely die from cervical cancer (Krishnan, 2008). The burden of cervical cancer mortality falls most heavily among the poorer women of the world. Cervical cancer represents the second most common

gynecologic malignancy diagnosed in the United States. Approximately 11,270 new cases of invasive cervical cancer were diagnosed in 2009, with an estimated 4,070 deaths (American Cancer Society, 2009). Disparities, treatment, and outcome for cancers in minorities and Caucasians have been documented (Brookfield, Cheung, Lucci, Fleming, & Koniaris, 2009). According to the CDC, between the years 1998-2003 the incidence of cervical cancer deaths was highest for Hispanic women (14.2 per 100,000), followed by African American women (12.6 per 100,000, and Caucasian women (8.4 per 100,000; CDC, 2009f; see Appendix E). More African American and Hispanic women get cervical cancer and are diagnosed at later stages of the disease than Caucasian women, possibly because of decreased access to Pap smear screening or follow-up treatment (CDC, 2009f). If the government truly wants to prevent cervical cancer they should mandate annual exams for women. If caught early enough cervical cancer is a treatable disease.

While cervical cancer rates have drastically fallen in developed countries due to effective preventive methods and treatments, socially disadvantaged women within these countries remain disproportionately more likely to develop and die of cervical cancer (World Health Organization, 2007). Further, in most developing countries, in contrast cervical cancer rates have risen or remained unchanged (World Health Organization, 2007). More than 83% of the 493,000 incident cases of cervical cancer, and an even higher proportion of the 273,000 related annual deaths, occur in the developing countries of sub-Saharan Africa, Latin America and the Caribbean, South and South-East Asia, and Melanesia (World Health Organization, 2007). Cervical cancer is the primary cause of cancer-related deaths and years of life lost among women in developing countries (Parkin & Bray, 2006). These women are more likely to be diagnosed with late-stage disease, receive either no treatment or treatment that does not meet currently accepted standards

of care, and suffer without the benefit of pain control and other palliative care (Parkin & Bray, 2006). These social disparities in prevention, incidence, detection, treatment, and survival are avoidable, but are not avoided. For these reasons, cervical cancer is a health inequity.

Margaret Whitehead has defined health inequity as, “differences in health that are not only unnecessary and avoidable, but in addition unfair and unjust” (1992, p. 429). Paula Braveman (2006) has argued that healthcare inequity is identified by the systematic tracking of health disparities within the social hierarchy, which consists of the different relative positions of social advantage and disadvantage as defined by race, class, gender, wealth, income, education, occupation, and geographic residence. Where there is health inequity, groups who have persistently experienced social disadvantage or discrimination in the past systematically experience greater health risk and worse health outcomes than the most advantaged social groups (Braveman, 2006). With this being said, cervical cancer is a striking case of health inequity. Women belonging to disadvantaged social groups are disproportionately more likely to develop and die from cervical cancer across and within countries. The vast majority of the incident cases of cervical cancer and related deaths annually occur in developing countries (World Health Organization, 2007).

Cervical cancer is often a preventable disease. The prevention of cervical cancer is based on the discovery that infection with one or more high-risk types of HPV is a necessary cause of cervical cancer (Walboomers et al., 1999). HPV infection is a highly prevalent STD and most women will be infected during their lifetime, with high rates in young women following sexual debut (Krishnan, 2008). While most infections are asymptomatic and transient, persistent or chronic infection over decades with the high-risk HPV type is associated with pre-cancerous lesions of the cervix that may progress to cervical cancer (Krishnan, 2008).

Several factors are associated with increased risk of both initial infection with high-risk HPV types and developing cervical cancer once infected. These individual factors include both biological factors, such as coinfection with other STDs or immunodeficiency; and behavioral factors, such as nonuse of condoms, multiple sexual partners, and young age at sexual debut (World Health Organization, 2007).

While differences in individual factors may have some effect on social disparities of cervical cancer, they are not considered the dominant cause of the inequitable social distribution. The most important determinant of social disparities in cervical cancer is the access to cervical screening and preventive vaccines (Denny, 2008).

Cervical screening allows for the early detection, follow-up and treatment of precancerous cervical abnormalities. It is a viable and highly effective preventive strategy because of the prolonged progression from infection to disease. In countries that have implemented high-quality screening programs using the Pap smear exam, societal average cervical cancer incidence and mortality rates have dramatically decreased (World Health Organization, 2007). Screening programs in most developing countries are insufficiently available and of poor quality, which results in much lower screening coverage and contributes to higher cervical cancer incidence and mortality (Denny, 2008). Screening coverage in developing countries is, on average, 19% compared to 63% in developed countries (Denny, 2008). In countries with screening programs, disadvantage social groups are disproportionately represented among the unscreened and the untreated (Denny, 2008).

Social disparities in demand and utilization result from government failure to ensure screening programs are accessible and acceptable to all (Erdman, 2009). Programs are implemented without sufficient attention to the conditions that render screening less or

inaccessible to disadvantaged social groups, including: lack of information, undervaluing of preventive care, lack of public health care facilities, sexual health stigma and related privacy concerns.

Information is an important dimension of accessibility (Erdman, 2009). Underutilization of screening services is commonly attributed to poor awareness of and information about cervical cancer and the benefits of screening in prevention and early detection (Erdman, 2009). Failure to appropriately distinguish among screening, diagnosis, and treatment, for example, may adversely affect demand for screening. A positive HPV test may be mistaken as a diagnosis for cancer and as such, falsely regarded as an untreatable disease. The psychological and financial burden of a perceived fatal diagnosis may deter women from screening. A mistaken understanding of cervical cancer screening means that this preventive care can itself be a barrier to access, given the low priority assigned to asymptomatic screening. Economic barriers and social norms contribute to the under valuing of preventive care (Erdman, 2009). Given that screening does not provide any immediate health benefits, its value may be discounted and deemed insufficient to warrant expenditure of scarce healthcare resources.

A second and complementary alternative measure focuses on the primary prevention of cervical cancer: the HPV vaccine. Studies indicate that the HPV vaccine, if made accessible to adolescent women in developing countries, can prevent almost 4 million cervical cancer deaths in the next decade (Goldie, O'Shea, Diaz, & Kim, 2008). And yet, the HPV vaccine is the most expensive vaccine in human history, priced at approximately \$360 wholesale for the currently recommended regime of three doses.

The statistics regarding the disparity of cervical cancer is not new information. This data has been collected for over 30 years. Yet, Merck has priced the vaccine at such a high rate that

the women who need it the most do not have economical access to it. The vaccine is being sold to the very people who need it least: the well-insured daughters of the middle class in the United States and wealthy developed countries. The vaccine is marketed to those with social and financial capital to access vaccination programs, the very women most likely to also have access to effective screening and treatment (Outterson, 2009). Liz Szabo, a journalist for *USA Today*, has written, “Some doctors now question whether the vaccine has been overpromoted to affluent women who need it least instead of patients most at risk of dying from the disease” (2009, ¶1). Merck’s marketing campaign suggests that all women are at risk of contracting cervical cancer – a strategy that helps them sell as many vaccines as possible. Because cervical cancer does not strike women equally, Charlotte Haug, editor of the *Journal of The Norwegian Medical Association*, states, “Vaccinating women who already get annual exams does little to reduce the number of deaths” (Szabo, 2009, ¶6). With this knowledge, Merck seems motivated by more than altruism. It is estimated that if Merck’s HPV vaccine becomes mandated it will generate annual sales of \$3.2 billion by 2010 (Allen, T., 2007).

The U.S. government does not regulate drug prices as do many other countries; Merck can set the price of its vaccine at a rate it thinks the market will bear (Angell, 2005). In other words, the vaccine is prioritized to the women who can pay the high price but need it least. Paradoxically, the circumstances of the HPV vaccine contribute unfavorably to the maintenance of existing health disparities rather than to enhancing the likelihood of overcoming them.

Adding to this travesty is what issue dominates the HPV vaccine literature. In most of the articles that discuss the HPV vaccine *controversy* there is some pronouncement to the claim that this vaccination will increase the sexual promiscuity of adolescent girls; very little is written on the glaring global health inequity that HPV and cervical cancer pose to disadvantaged women.

The discussion needs to be moved away from the “license to have sex” discourse and on to what can be done to distribute this vaccine to the women who need it most – women who are members of disadvantaged minorities.

Challenges in Introducing HPV Vaccine in Developing Countries

Affecting relatively young women, cervical cancer is the largest single cause of years of life lost to cancer in the developing world. The deaths of women who are in their most productive years have a devastating effect on the well-being of their families, resulting, for example, in decreases in school attendance and nutritional status among their children (Agosti & Goldie, 2007).

In order to decrease the number of cervical cancer deaths in developing countries a screening program complemented by access to the HPV vaccine must be implemented. The United States and Europe both experienced high rates of cervical cancer well into the twentieth century, until screening and treatment programs were established by national health services (Gustafsson, Ponten, Bergstrom, & Adami, 1997). In the United States, for example, rates have fallen by 75% or more since the 1960s, when screening was instituted (Kitchener, Castle, & Cox, 2006).

The differences in disease burden are due primarily to stark differences in both the availability and the utilization of screening and treatment services. While screening with Pap smear exams has become a staple of women’s health care in the developed world, very few women in the developing world have access to such screening (Kitchener et al., 2006). This is due in large part to the difficulties governments face in establishing complex laboratory services that require coordinated, multi-visit screening and treatment services, and the inherent limitations in the screening procedure itself (Kitchener et al., 2006). In addition, cultural, social, and

economic constraints keep women from taking advantage of these services when they are available (Outterson, 2009). These constraints include the social stigma associated with STDs and with gynecological exams, the low status of women and their health needs in many societies, and the direct and indirect costs associated with clinic visits (Outterson, 2009). These constraints could be narrowed with the introduction of the HPV vaccine in developing countries.

Consideration for policymakers debating the use of the HPV vaccine in any particular country will include that country's disease burden, its health care infrastructure, and its capacity for initiating and sustaining an immunization program for adolescents. Other considerations include the affordability and cost-effectiveness of vaccination relative to other programs competing for resources and the likelihood of cultural acceptability, political will, and public support.

Ultimately, the effectiveness of the HPV vaccine will require improved systems for providing health care to adolescents. Sociocultural sensitivities in the area abound, although concern about vaccinating adolescents against a sexually transmitted disease have been tempered by an emphasis on the vaccine's role in cancer prevention. Yet in countries characterized by mistrust of governmental health care initiatives, vaccination programs targeted toward young women may be misunderstood as attempts to control fertility – misapprehensions in some countries have occurred even with the polio and tetanus vaccines. If such fears can be alleviated, an adolescent immunization program, possibly school-based or a community outreach program, could be designed to deliver adolescent health services and immunizations against tetanus, measles, rubella, meningococcus, typhoid, as well as HPV. In areas where the rate of school enrollment among girls is low, community-based efforts to reach girls outside school must be evaluated.

The factors with the greatest influence on the cost-effectiveness of vaccination will be the price of the vaccine and the costs of a program to reach adolescents. First and foremost the price of the HPV vaccine will need to be addressed. Dramatic price tiering will be required to facilitate its timely use in developing countries. According to the WHO, manufacturers of the HPV vaccine have declared that they are willing to set different prices for countries with different economic conditions (World Health Organization, 2007).

The GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunizations) – a partnership of national governments, the WHO, The World Bank, The Bill and Melinda Gates Foundation, the vaccine industry, public health institutions, and nongovernmental organizations – provides technical assistance and financial support for vaccines in countries with a gross national income of less than \$1,000 per capita, as well as in China, India, and Indonesia. With subsidies from GAVI, HPV vaccine can be brought to the poorest parts of the world. In October 2008, the GAVI Alliance board agreed to prioritize HPV vaccines along with new vaccines against typhoid, Japanese encephalitis, and rubella (GAVI Alliance, 2009).

Through large-scale purchasing power, GAVI estimates it can bring the cost of the HPV vaccination down to a fraction of the current price. In Kenya, for example, it is estimated to cost \$8-\$25 per vaccinated girl, including delivery and administration (GAVI Alliance, 2009). Physician Lob-Levyt described a recent recommendation on cervical cancer by the WHO's Strategic Advisory Group of Experts (SAGE) as a "stepping stone on the way to more equity in global health" (GAVI Alliance, 2009, ¶9).

Mandating the HPV Vaccine for Girls Only Violates Title IX

Having played college basketball for a Division I university, I have some experience with Title IX of the Education Amendments of 1972. Currently, ACIP recommends that all 11- and 12-year old girls be vaccinated, as well as all females 13 to 26 not previously vaccinated, and upon recommendation of their physicians (CDC, 2009a). Although the ACIP recommendations do not translate into vaccination requirements by individual states or mandatory insurance coverage, state health authorities and private insurers usually follow the ACIP's suggestions (Cook, 2008).

If state governments mandate the HPV vaccine for school enrollment it will violate Title IX. A girls-only mandate could also violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution.

Title IX of the Education Amendments of 1972 has stated that, “[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance” (Education Amendment of 1972). The Department of Education’s Office for Civil Rights, which has been delegated the task of interpreting Title IX, has stated, “Title IX applies to all public and private educational institutions that receive federal funds, i.e., recipients, including, but not limited to, elementary and secondary schools, school districts, proprietary schools, colleges, and universities” (Cook, 2008, p. 221). Nearly all educational institutions receive federal financial assistance of some sort, even if through only one program like the school lunch program. This federal financial assistance brings the educational institution under the purview of Title IX.

Since most schools receive federal funding, it could be argued that legislation compelling only girls to be vaccinated for HPV as a condition for school enrollment is a violation of Title IX because it denies girls participation in school based on gender. Currently, there is no reported case law addressing an issue comparable to legislation requiring only single-sex vaccination as a condition of school attendance, so it is unclear how a state court would analyze such a case (Cook, 2008).

The Equal Protection Clause of the Fourteenth Amendment of the United States Constitution states that no person shall be denied “the equal protection of the laws.” The Supreme Court has interpreted the Equal Protection Clause to require that, when a law or policy imposes a different standard or burden on one gender, the government must prove an “exceedingly persuasive justification” for that sex-based classification (Cook, 2008). Obliging girls to receive an HPV vaccination could potentially violate the Equal Protection Clause if the legislation has no such exceedingly persuasive justification for its sex discrimination.

Until the HPV vaccine is approved for boys, and a mandated HPV vaccine law is gender neutral, the rights of girls under Title IX and the Equal Protection Clause are protected.

Vaccination of Males May Protect Them

The HPV vaccine is the first to be mandated for only one gender. This is likely because the vaccine was approved for girls and not boys, and most research has focused on HPV infection in women because of the association between HPV infection and cervical cancer (Dunne, Nielson, Stone, Markowitz, & Giuliano, 2006). Data demonstrating the safety and immunogenicity of the vaccine are available for males aged 9-15 years. Three Phase 1 studies demonstrated that safety, tolerance, and immunogenicity of the HPV vaccine were similar to men and women (Partridge & Koutsky, 2006). The first two studies focused on HPV 16 and 11

respectively, while the third study demonstrated high levels of immunogenicity to the HPV vaccine 6/11/16/18 vaccine in 10-15-year-old males. Phase III clinical trials examining the vaccine's efficacy in men and adolescent boys are currently underway, with results available in the next couple of years (Partridge & Koutsky, 2006). On September 9, 2009, an advisory panel of the FDA voted in favor of the safety and efficacy of Gardasil® to inhibit genital warts in boys and men ages 9 to 26 (Singer, 2009). The FDA typically has followed the recommendations of such panels on drug approvals.

HPV infection is common among men. One percent of the male population aged 15-49 years had genital warts, with peak incidence in the 20-24-year-old age group. A recent cohort study found the 24-month cumulative incidence HPV infection among 240 men aged 18-20 years to be 62.4%, nearly double the incidence of their female counterparts. This result may have been due to the increased sensitivity of HPV testing procedures used in the study. Nonetheless, the results reaffirm that HPV is common and multifocal in males. Men are also at risk for HPV-related anogenital cancers. Up to 76% of penile cancers are caused by "high-risk" types of HPV. Fifty-eight percent of anal cancers in heterosexual men and 100% percent among homosexual men are positive for the "high-risk" types of HPV. Therefore, assuming vaccine efficacy is confirmed in males, they also could be protected through HPV vaccination. Men are assumed to be the major reservoirs of genital HPV infection for women, although comparatively little is known about the natural history of HPV in men (Hernandez et al., 2008).

After viewing the literature on vaccinating boys with the HPV vaccine, I found an interesting paradigm that is worth noting. When the HPV vaccine was approved for girls as young as 9-years-old in 2006, some critics touted that the drug might encourage girls to be more promiscuous and practice risky sexual behavior (Krishnan, 2008). Now that the drug is being

considered for boys of the same age, the issue has shifted to cost effectiveness and safety. Not one piece of literature that I read indicated a concern for an increase in male promiscuity. “We are still more worried about the promiscuity of girls than the promiscuity of boys,” said Susan Reverby, a Wellesley College professor (Should the FDA Approve Gardasil® for Boys, 2009, p. 9). She continued to assert the “There’s a double standard” (p. 9). This is another example how women are devalued in our society by placing more emphasis on our sexual lifestyle and not our safety. Delores Liston and Regina Moore-Rahimi (2005) write:

Based on our research, we are convinced that shifting and oftentimes mutually contradictory criteria form a double standard that perpetuates the marginalization of women in our contemporary landscapes and holds women in condemnation almost regardless of what they do or say. (p. 212)

Vaccinating Both Sexes May Better Protect the Public

Bioethical feminists Adrienne Asch and Gail Geller (1996) have written, “Because women’s lives are inextricably intertwined with those of their intimate partners, there are no women’s issues that are not also issues for those partners” (p. 334). Since HPV is transmitted between sexual partners, some experts think the virus will not be sufficiently contained until boys also receive HPV vaccinations also (Krishnan, 2008).

Early studies have shown Merck’s HPV vaccine to be both effective at producing immunity in boys and safe to use. A 2007 study tested the safety and immunogenicity of the HPV vaccine on preadolescents and adolescents of both sexes (Reisinger et al., 2007). The study found that in 9- to 15-year old adolescents, the HPV vaccine was generally well tolerated and induced persistent immune responses in the majority of subjects for at least 12 months following the completion of the third dose (Reisinger et al., 2007). They concluded that the vaccine

durability supports universal HPV vaccination programs in adolescents to reduce the burden of HPV disease, particularly cervical cancer and precancers (Reisinger et al., 2007). It has been licensed for males in 25 nations of the European Union and in Australia. In the United States, however, the FDA requires proof that the vaccine actually prevents infection. Currently, the FDA is considering approval of Merck's HPV vaccine for the prevention of genital warts in males (Singer, 2009). Merck is hoping to expand its drug licensing to include the prevention of HPV-related cancers in males (Singer, 2009).

Studies have identified HPV DNA on male genitalia, anal mucus and in the oral cavity. Peak incidence was found in men between ages 30 and 39 (Dunne et al., 2006). Penile HPV prevalence rose with increasing number of sexual partners (Dunne et al., 2006). Overall, HPV prevalence appeared to be lower in men than women, suggesting penile tissue could be less receptive to high-risk HPV (Dunne et al., 2006).

When one evaluates the mode of transmission of HPV, it stands to reason that a population would be more efficient at reducing infection that both males and females can transmit if they are both protected with the vaccine. A mathematical modeling study was published in 2007 that assessed HPV vaccination strategies. The authors concluded that that vaccinating 70% of girls before age 12 years would reduce the incidence of genital warts (83%) and cervical cancer (78%) due to HPV types 6, 11, 16, and 18 (Elbasha, Dasbach, & Insinga, 2007). When they added vaccinating boys and men to this model, they concluded that there would be further reduction of the incidence of genital warts (97%), cervical dysplasia (91%), and cervical cancer (91%) (Elbasha et al., 2007). This model was limited to cervical cancer, cervical dysplasia, and genital warts. This model did not take into account a possible reduction in HPV-related anal, head, and neck cancers. As more favorable data are collected in relation to

vaccinating both genders, the FDA could eventually recommend that all boys be vaccinated with the HPV vaccine in the near future.

These last two sections focused on how HPV and the vaccine relates to boys and men. One might wonder why I chose to include these sections in a bioethical feminist inquiry. From all the reading I have done on bioethics and feminism I have come to realize that bioethical feminist theory does not discriminate based on class, race, and gender. Its goal is to end oppression, discrimination, and marginalization of all people, not just women. I chose to add the sections about HPV and men because if the vaccine could be useful in preventing genital warts, anal, penile, or throat cancers then they should be afforded every opportunity to have access to the vaccine. Withholding this vaccine from men also marginalizes them.

The current FDA approval for the vaccine is for women only. This sequestering of a single gender also highlights how women are punished for their sexual behavior whereas men are excluded from taking any responsibility for the spread of the disease. Men should be included as viable recipients for the vaccine to ensure the reduction of the four types of HPV being spread throughout the population.

Summary

Cervical cancer is a classic example of inequity, in the differential impact it has on women in low- and middle- income countries, with higher incidence and higher mortality than in wealthy countries. Cervical cancer remains a major killer of women globally, even though the disease has declined dramatically in developed countries with the advent of reliable Pap smear testing. The HPV vaccine could have its biggest impact in high-risk areas. But the poverty that limits Pap smear screening in the developing world – causing the disparities in global cervical cancer rates – will also affect vaccine distribution. The advent of new vaccines that could prevent

more than half the cases of this deadly disease raises the possibility that this disparity could be reduced eventually, even without massive investments in cervical screening services. However, the promise that the vaccine offers can only be realized if it reaches those who need it most, and without delay that often befalls new health technologies. While clearly there are challenges that could cause delays or leave important groups of girls without the protection they need, there are also potential remedies for these barriers that are feasible. Vaccine delivery through schools and perhaps community outreach mechanisms appears to be both affordable and acceptable methods of distribution. Financing remains a substantial challenge, especially in light of the current economic crisis. Low-income countries must look to the GAVI Alliance for subsidies both to purchase vaccine and the operational costs of vaccine delivery.

Another bioethical feminist issue that arises when discussing the possibility of mandating the HPV vaccine for girls and not boys in the United States is the fact that it would violate their constitutional rights afforded to them through Title IX and the Fourteenth Amendment.

The final bioethical feminist issue is the impact of the HPV vaccine on boys and men. Like women, men suffer from HPV-related cancer and genital warts. Early clinical trials with boys show a significant immune response to the HPV vaccine. There are also data that shows the vaccine to be safe and well tolerated in males. With this being said, men should be afforded the opportunity to receive the HPV vaccine in order to protect them from genital warts and HPV-related cancers.

CHAPTER 8

CONCLUSION

Human papillomavirus, or HPV, is a highly contagious sexually transmitted disease that causes cervical cancer in women. Gardasil®, The HPV vaccine produced by Merck & Company, prevents four types of HPV, including two of the most dangerous variants that are responsible for 70% of cervical cancer and two types that cause 90% of the cases of genital warts. In the summer of 2006, a federal vaccine advisory panel to the FDA voted unanimously to recommend the HPV vaccine for women and adolescent girls. In one respect, this new vaccine is a common-sense addition to an established national vaccine schedule as lengthy as it is routine. Unlike already familiar vaccines that target all children entering school, the FDA advisory panel recommends the HPV vaccination only for girls and young women ages 11 to 26. Gardasil® combats an STD that, often asymptotically, hides itself in women, potentially triggering a deadly cancer. The HPV vaccine is therefore without precedent in that it forces the American public to evaluate what it means to protect women, what women need protection from, and what price our society is willing to pay to provide that protection.

The Connection to Curriculum Studies

The completion of this dissertation encompasses the very goal of curriculum studies. William Pinar (2004) states, “The school curriculum communicates what we choose to remember about our past, what we believe about our present, what we hope for the future” (p. 20). By sharing my pathography I have helped readers remember the past. By discussing the current HPV vaccine debate I have invited readers to focus on the present. I have likewise invited readers to join me in the hope for the future that includes the reduction of cervical cancer worldwide.

In completing this dissertation I hope to have made a niche in the curriculum studies field for medicine, science, and bioethics. The kinds of debate I presented in this dissertation must be discussed in the curriculum studies field. Science and medicine are such a big part of American society that as educators we would be remiss not to critically discuss these topics within the walls of our schools. William Pinar has written:

If public education is the education of the public, then public education is, by definition, a political, psycho-social, fundamentally intellectual reconstruction of self and society, a process in which educators occupy public and private spaces in-between the academic disciplines and the state (and problems) of mass culture, between intellectual development and social engagement, between erudition and everyday life. (2004, p. 15)

As educators we must engage our students in conversations that involve the political, social, and ethical dilemmas of our society. If we do not, we are educating a class of mindless, non-critical thinkers who will become a drain on society instead of becoming productive members of a community.

Possible Future Studies

When I was in the process of orally defending this dissertation to my committee, the FDA recommended Gardasil[®] for boys and men in order to prevent genital warts. According to the FDA, genital warts affect 2 out of every 1,000 men in the United States (Food and Drug Administration, 2009). It would be interesting to conduct a study ascertaining how many parents would be willing to vaccinate their boys against a disease that is not life threatening.

I would also like to do a qualitative analysis on what girls and women know about HPV and its connection to cervical cancer. It would be interesting to see how many women understand the importance of having annual exams.

Summation

Following FDA approval, the National Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination for girls ages 11-12 with three doses of the HPV vaccine. Thereafter, state legislatures around the country engaged in an intense effort to pass laws mandating vaccination of young girls against HPV. This activity was spurred in part by an intense lobbying campaign by Merck.

The United States has a robust state-based infrastructure for mandatory vaccination that has its roots in the nineteenth century. Mandating vaccination as a condition for school entry began in the early 1800s and is currently required by all 50 states for several common childhood infectious diseases. Some suggest that mandatory HPV vaccination for minor females fits squarely within this tradition.

Nonetheless, state efforts to mandate HPV vaccination in minors has raised a variety of concerns on political, social and bioethical grounds. Unlike other diseases for which state legislatures have mandated vaccination for children, HPV is neither transmittable through casual contact nor potentially fatal during childhood. It also would be the first vaccine to be mandated for use exclusively in one gender. As such, HPV vaccine presents a new context for considering vaccine mandates.

In this bioethical feminist theory inquiry, I reviewed the scientific evidence supporting the HPV vaccine's approval and legislative actions in the states that followed. I presented the reasoning behind the government's push to mandate the vaccine for adolescent girls. The logic for mandating the HPV vaccine begins with the fact that it is a remarkable biomedical and public health achievement. Research confirms that HPV is responsible for 99% of the cases cervical cancer, and the technology now exists to help prevent women from developing HPV-16 and -18

induced cervical cancer. Second, administering the HPV vaccine is cost effective and significantly saves health care dollars otherwise spent on diagnosis and treatment of this preventable disease. Furthermore, it eliminates the negative emotional and psychological feelings that can follow such a diagnosis. In addition, school-aged children are the appropriate population to whom to administer this vaccine because it must be given before the onset of the first sexual experience. Moreover, previous school-wide vaccination programs demonstrate that this is the optimal venue for rapid and widespread immunity. Finally, the medical community claims that the HPV vaccination is not synonymous with support and approval of promiscuity, but rather a cry to rally together to eradicate cervical cancer worldwide. Therefore, this public health breakthrough should not be associated with promoting sexual activity in adolescent girls, but rather promoted as a responsible and necessary step in protecting children's future health. Cancer is a public health challenge that needs to be conquered; it is not an appropriate venue for political or ideological debate.

I then argued that mandatory HPV vaccination at this time is both unwarranted and unwise. While the emergence of an HPV vaccine reflects a potentially significant public health advance, the vaccine raises several concerns. First, long term safety and effectiveness of the vaccine are unclear. Second, the legal and ethical justifications that have historically supported state mandated vaccination do not support mandating the HPV vaccine. Specifically, HPV does not threaten an imminent and significant risk to the health of others. Mandating the HPV vaccine would therefore constitute an expansion of the state authority to interfere with individual and parental autonomy. Engaging in such expansion in the absence of robust public discussion runs the risk of creating a public backlash that may undermine the goal of widespread HPV vaccine coverage and lead to public distrust of established childhood vaccine programs for other

diseases. Third, the current sex-based HPV vaccination mandates present constitutional concerns because they require only girls to be vaccinated. Such concerns could lead to costly and protracted legal challenges. Finally, vaccination mandates will pose economic burdens on federal and state governments and individual practitioners that may have a negative impact on the provision of other health services.

Finally, I moved the debate to the ethical issues that arise when discussing mandating the HPV vaccine for girls and how cervical cancer is a disease that produces a health inequity. Globally, 80% of cervical cancer cases arise in developing countries due to disparities in access to cancer screening resources. Similar disparities exist in the United States, where the impact of cervical cancer on minority populations is disproportionate. Compounding the access problem, Merck's HPV vaccine's \$360 price tag makes its three-shot, 6-month regimen among the most expensive vaccines ever marketed. In absence of government intervention, therefore, those most in need of this vaccine will also be those least able to afford it.

In discussing the political, social, and bioethical controversies that surround the HPV vaccine, I have presented a complete picture of a significant health issue that affects not only women, but all of us.

Implications for the Future- Comes Down to Open and Clear Communication

There were legitimate scientific reasons to promote the use of this vaccine. It is very effective and has minimal known side effects. It needs to be administered before exposure to HPV, so giving it to children makes sense. The HPV vaccine could have especially huge benefits if it were used widely in developing countries, where Pap smears are not common and cervical cancer kills hundreds of thousands of women. But the push to mandate its use in the U.S. was too

early, too aggressive, and – most important came from the wrong advocate (politicians and a large drug company).

This vaccine still faces plenty of scrutiny. The marketing of this vaccine as a cancer vaccine is inaccurate. It is not a cancer vaccine. It is a vaccine against a virus that may cause cancer; the types of HPV not covered by the vaccine cause approximately 50% of abnormal Pap smears and 30% of cervical cancers (Krishnan, 2008). Indeed, according to the FDA, the studies used to approve Gardasil® proved it prevented development of pre-cancerous lesions but could not prove it prevents cancer, since “the study period was not long enough for cervical cancer to develop” (FDA, 2006, ¶2). One must hope that being vaccinated won’t lead women to a sense of complacency about getting yearly Pap smears, since that could lead to an increase in deadly cancers (Bevington, 2007). Given these indiscretions, Merck started to feel pushback first from anti-vaccination groups, then concerned parents and citizens. Merck has since decreased its marketing and lobbying effects.

The biggest future challenge that the HPV vaccine will face is in communication of information between the patient and the medical and political communities. The entire controversy surrounding the HPV vaccine is a result of a communication gap between those making the medical decisions, those enforcing public health policy, and those on the receiving end of those policies. Matthew Wynia (2007b) has written, “Success in public health relies on public trust” (p. 4). Even with the trust of the public, communicating about vaccines poses a number of special challenges.

First, like other vaccines, they are often seen as “treatment” for a disease one doesn’t have (Allen, A., 2007). Convincing someone to receive treatment to prevent a future disease can be difficult. Some might say this is a moot point because vaccine compliance rates are very high

in the United States. This is true for the vaccines that prevent contagious diseases. When dealing with the HPV vaccine and the disease it prevents the issue is more problematic because some may say, contracting an STD was based on a behavioral choice and not by chance. Overcoming this issue will have to come from a trusted health authority. Bioethics attempts to foster positive and personal relationships between patient and physician. This personal relationship based on trust and confidence will be imperative to improve uptake of the HPV vaccine especially when dealing with parents and their adolescent children.

Second, the diseases in question may be scarce or, ironically, become scarce because vaccination ensures their demise. This makes it increasingly difficult to convince people that any perceived risk of vaccination is worth it, since the infection in question eventually comes to be perceived as not a threat. In short, vaccines can become victims of their own success. For example, when is the last time you saw a child crippled by polio or disfigured by smallpox? HPV is not a scarce disease, in fact is the most prevalent STD in the United States. The issue with cervical cancer is that it is not found in epidemic portions in the United States. Far more women die from heart disease (approximately 329, 238 heart disease related deaths in women in the United States in 2005) and breast cancer (approximately 41,116 deaths in 2005) than from cervical cancer (approximately 3600 deaths in 2005; CDC, 2009g). Convincing parents to vaccinate their young daughters for a disease that is not perceived as immediately life threatening will be difficult.

Third, because vaccination is so common, it is often blamed for other, random events. It is very difficult – some say impossible – for us as humans to understand or accept randomness in our lives. As a result, we create links and patterns even where there are none. So when we receive a flu vaccine and the next day come down with a cold, we perceive a link even though

the flu vaccine contains no virus and is typically delivered at just the time when catching cold is common. This becomes even more of an issue when a child receives a vaccine and then has a seizure, or is diagnosed with autism, or develops liver failure. Scientific based studies that disprove claims of causality in such situations are virtually impossible to believe for parents who see an obvious pattern staring them in the face. As it stands now, the CDC claims that the HPV vaccine is safe and causes no major complications upon administration. With the HPV vaccine being so newly introduced on the market long-term data are not available. Physicians and parents will need to continue to monitor the CDC's vaccine website for any major complications or side effects due to the HPV vaccine. The website is <http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm>. The CDC also produces a vaccine information sheet that summarizes all pertinent information pertaining to the vaccine (see Appendix F).

Finally, Merck has faced a special problem communicating to the public about this vaccine – namely because it protects against an STD. Religious conservatives were bound to play the promiscuity card and argue against vaccination of girls without raising promiscuity issues about vaccinating boys, just as they did with the Hepatitis B vaccine. To vaccinate girls against an STD, the argument goes, is to give them a license to have sex. Of course by this same argument, a vaccine for heart disease should be opposed because it would encourage unhealthy eating, and wearing a motorcycle helmet would promote reckless driving. There is simply no evidence that vaccination against an STD increases sexual promiscuity (Monk & Wiley, 2006). What I have found more egregious is the fact that promoting abstinence should rely on threatening those who decline to be abstinent with the risk of getting cancer. Merck will need to re-educate the public with the latest efficacy and safety findings. They will need to be more transparent to the public about why the vaccine has a \$360 price tag, especially when we review

the incidence of HPV infection and cervical cancer. The facts state that that the women who have the highest incidence of cervical cancer are the ones with the least amount of money.

Overcoming communication challenges like these demands clear and effective communication by a trusted health authority. Lack of trust will breed both fear and non-adherence. Public health is, after all, a public endeavor (Wynia, 2007b). Public health institutions and those in the pharmaceutical industry should be concerned with maintaining their trustworthiness not their bank accounts. They should be prepared to back up their recommendations with rock-solid science, especially in making recommendations. Ensuring that information is consistent and clear is also key. Bioethical feminists Alisa Carse and Hilde Nelson (1999) write, “When we are in conditions of dependency, we must often place presumptive faith in those entrusted with our welfare, relying on them not to exploit our vulnerability or to abuse the power we have given them” (p. 26). That’s where Merck lost its way. Some in the public health community warned Merck not to pursue an aggressive lobbying campaign because they knew that, in the end, it could tarnish the entire public health communication endeavor. Public trust relies on a clear separation between those making the money on vaccination and those making the decisions about which vaccines to recommend or mandate.

Suggestions

Before government officials decide whether the HPV vaccine should be mandated, ethical concerns must be alleviated. There are three complementary steps that can help calm parental fears and promote the purpose of this vaccine: to save the lives of women. First, the public must realize that the HPV vaccine has the potential for decreasing the number of women who contract HPV-related cervical cancer. There must be a clear understanding by the public that HPV is a sexually transmitted disease that is linked to several different cancers found in both

men and women. How is this accomplished? Not through abstinence-only education programs. Schools must be realistic in today's world where adolescents are exposed to tremendous amounts of media that promote promiscuity, physical beauty, and sexual innuendoes. Schools and community organizations where adolescent education takes place must incorporate a comprehensive sexual education program that includes abstinence education, but also includes educating about safe sex practices; teen pregnancy; positive self-image; and incidence of sexually transmitted diseases, especially the link between HPV and cervical cancer.

Second, public health officials need to stress that the reason it must be given early in life is that inoculation at that point provides that best chance of lifetime protection. Last and most important, there must be a complete separation of the medical matter of preventing cancer from the moral matter regarding premarital sex. Health officials must make serious attempts to reach out to the religious community, which has moral qualms. Perhaps Merck can circumvent this controversy. While promoting the inclusion of Gardasil® as a standard or required form of vaccination, the company might also work with family-focused groups who oppose sex outside of marriage to co-develop educational tools for discouraging premature sexual relationships citing medical, emotional, and practical reasons for doing so. If these three issues are addressed, the government will not have to mandate Gardasil®, because parents will understand that they are protecting their daughters against the second leading cause of cancer death in women.

The HPV vaccine is an important part of the cervical cancer management picture, but not the whole solution. Greater awareness of disease risks, safe sex, condom use, and improved “opt-in” cervical cancer screening should also have been promoted. If Merck had run a public health education campaign, rather than simply plugging its product, Gardasil® might have had a better reception, and the real issue of saving women's lives could be realized.

One Last Thought

I truly believe that the HPV vaccine is a great medical advancement for all men, women, and children. It is the first vaccine that has the potential of preventing cancer. After 2 years of reading, research, and thorough scrutiny of the vaccine, I do not believe that this immunization should be mandated. The decision to receive this particular vaccine must be left up to parents and family health providers. I do have concern for the marginalized girls who need this vaccine the most, and am comforted in knowing as long as the government provides the funds for the Vaccines for Children program they will have access to the HPV immunization. If this financing ever changes, I would ultimately support a government mandate to ensure that all girls will have access to the vaccine. My question to Merck would be, “Why is Gardasil[®] still being sold in the U.S for \$360 when the GAVI Alliance acquires the vaccine for roughly \$25 per immunization?”

For some families this vaccine is a welcome advancement; for others it poses an intrusion on family values and morals. Deciding to vaccinate one’s 11- or 12-year old daughter is a very personal issue and needs to stay within the family unit. Intrusion from the government represents a complete disrespect of one’s autonomy to make personal health care decisions. Even with my personal history of cervical dysplasia, I welcome this vaccine with open arms, but I want that to be my decision not the decision of my local politician.

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APPENDICES

Appendix A

Current introduced state-by-state legislation of the HPV vaccine

State	Legislative Summary	Status
Alabama	House Bill 42 – States that parents have the option to immunize; requires HHS to mail information to parents about relationship between HPV and cervical cancer.	Passed
Alaska	Requires offering a voluntary vaccination program	Passed
Arizona	Legislation introduced in 2006-2007 Senate Bill 1437—Allocate money for outreach and education programs; House Bill- 2086/ Senate Bill 1502 – requires insurance to pay for vaccine; Senate Bill 1093 – prohibit health departments from requiring vaccine	Pending
California	Requires health insurance plans that cover the treatment of cervical cancer to also cover the vaccine (Vetoed in 2008); Reintroduced in 2009-2010 term and is pending.	Passed by Senate; vetoed by Governor on 9/30/08. Now sits in a suspense file as of 07/09
Colorado	Senate Bill 80 – Require information to be given to parents about the HPV vaccine and requires the vaccine be given to girls before age 12 in order to attend school, does allow exemption if parent objects. House Bill 1016 – Request a Medicaid waiver from the federal government to provide HPV vaccine for girls 12-18 with parental consent Co Chapter No. 41 (2007) – Allocates 4% of state tobacco settlement money to cervical cancer immunization fund. Co. Chapter No. 212 (2007) – Include information on HPV and its link to cervical cancer along with information about the vaccine in sexual education classes at schools. Co. Chapter No. 318 (2007) – Creates cervical cancer immunization program. Adds vaccine to Medicaid benefits. Requires certain insurance programs to cover the vaccine.	Passed
Connecticut	House Bill 6977 – Would require the first dose of the HPV vaccine for girls entering 6 th grade.	Passed

Delaware	No legislation proposed.	
District of Columbia	Mandates that all girls receive the vaccine before that age of 13. Parents may opt-out.	Passed
Florida	Senate Bill 660 – proposed that certain students receive the HPV vaccine before entering school and would require public and private school to provide information on HPV and the HPV vaccine. No new legislation proposed.	Died in committee
Georgia	House Bill 736 – Would require public schools to offer parents of 6 th grade girls with information concerning HPV and the immunization.	Pending
Hawaii	House Committee Resolution 51 – Requests the health department to expand its educational programs to increase awareness by both men and women and suggest new and innovative measures to better distribute information in order to prevent cervical cancer with the goal of eventual eradication.	Pending
Idaho	No legislation proposed.	
Illinois	House Bill 115 – Would create an awareness campaign on HPV and cervical cancer; provides parents with information; would require girls to receive the HPV vaccine upon entrance into the 6 th grade. Bill allows parents to opt out. Senate Bill 10 – Would require the HPV vaccine for 11 and 12 year old girls, but allows parents to opt out. Also requires the school to track the number of immunized children attending school. Public Act 095-0422 (2007) – Requires insurance companies to provide coverage for the HPV vaccine.	Passed
Indiana	Public Law No. 80 (2007) (Senate Bill 0327) – requires parents of girls entering the sixth grade to receive information about the link between HPV and cervical cancer and the availability of the HPV vaccine. Parents of 6 th graders must sign a statement notifying the school of their decision to vaccinate or not vaccinate their child. School must provide this information to the state Health Department. Does not mandate the	Passed

	vaccine for school entrance.	
Iowa	House File 661 – would require insurance providers to cover the cost of the HPV vaccine for females 9-26 of age. House File 611 – Requires that educational materials for 7 th graders also include information on HPV and the availability of the vaccine.	Pending Passed
Kansas	House Resolution 6019 – Urges the FDA to use caution in approving new vaccines such as Gardasil®. House Bill 2227 – Would require vaccination for girls entering the 6 th grade. Also requires parents to receive information on the link between HPV and cervical cancer.	Pending Passed
Kentucky	House Bill 396 – Would require immunization against HPV for school-age children; requires parental statements to withhold consent to be filed with the immunization certificate.	Passed, sent to senate
Louisiana	House Bill 357 – Would require insurance companies to cover HPV vaccine. House Bill 359 – Would require schools to offer HPV information and vaccines under certain circumstances.	Pending Passed House and Senate; Gov. did not sign
Maine	Maine Chapter No. 73 – Establishes financial coverage of the HPV vaccine through the MaineCare program and improve public awareness of vaccine.	Passed
Maryland	Senate Bill 54 – Would require all girls entering 6 th grade to be vaccinated. Md. Chapter No. 191 – Establishes a task force for the HPV vaccine.	Withdrawn Passed
Massachusetts	Senate Bill 102 – Would require all 6 th grade girls to receive the HPV vaccine. Allows parents to opt out.	Pending
Michigan	House Bill 4164/4104 – Would require the HPV vaccine. House Bill 5171 – Would require all pupils and parents receive information regarding the HPV vaccine. House Bill 5322 – Would require schools to provide HPV information and vaccines under certain circumstances.	Pending Pending Passed

Missouri	<p>House Bill 802 – Mandates that girls entering the 6th grade receive the vaccine. Parents may opt out.</p> <p>Senate Bill 514 – Would provide parents information on HPV, cervical cancer, and the HPV vaccine.</p> <p>Would require health insurers to provide coverage for HPV screenings for cervical cancer.</p>	<p>Pending</p> <p>Pending</p>
Minnesota	<p>Senate File 243 – Would require the HPV vaccine for girls entering school at age 12. Provides parents with information and allows exemptions.</p> <p>MN Laws, Chapter 147 – Created a study to closely review the risks, benefits, availability, efficacy, and coverage of HPV vaccine.</p>	<p>Pending</p> <p>Passed</p>
Mississippi	House Bill 895 – Would require all girls entering 6 th grade to be vaccinated.	Died in committee
Montana	No proposed legislation.	
Nebraska	Legislative Resolution 170 – Would create an interim study of the HPV vaccine.	Pending
Nevada	NV Chapter No. 527 – Requires insurance companies to cover the cost of the HPV vaccine.	Passed
New Hampshire	Created a voluntary program which can provide the vaccine free to girls between 11-18.	Passed
New Jersey	Would require Medicaid, NJ FamilyCare, and the State Benefits Program to cover the cost of HPV vaccines.	Pending
New Mexico	<p>Senate Bill 407 – Requires insurance plans in the state to cover the FDA-approved HPV vaccine for girls 9 to 14.</p> <p>Senate Bill 1174 – Would require the HPV vaccine for girls between 9 and 14. Allows parents to opt out.</p>	<p>Passed</p> <p>Vetoed</p>
New York	<p>Would require girls born after January 1, 1996 to be vaccinated. Provides opt out clause for parents.</p> <p>Would require insurance companies that cover well-child visits and cervical screening to cover vaccine</p>	<p>Pending</p> <p>Passed</p>
North Carolina	Requires health department to provide educational information to parents of children in grades 5-12.	Passed

North Dakota	Provides funding for distribution of educational materials on HPV and the HPV vaccine.	Passed
Ohio	Would require all girls entering the 6 th grade to be vaccinated. Schools will not allow any student to attend classes for more than 14 days without written information on when they are receiving the vaccine. Parents are allowed to opt out.	Pending
Oklahoma	Senate Bill 487 – Would require HPV vaccine for all girls entering the 6 th grade.	Pending
Oregon	House Bill 3253 – Would require health benefits plans to cover the cost of the vaccine for girls 11 years or older.	Pending
Pennsylvania	House Bill 524 – Would require insurance policies to provide coverage for vaccine. House Resolution 42 – Would designate January as cervical cancer awareness month.	Pending
Rhode Island	House Bill 5061 – Would require insurance companies to cover vaccine.	Passed
South Carolina	House Bill 3136 – Would require 6 th grade girls to receive the vaccine. Allows for parents to opt out.	Pending
South Dakota	House Bill 1061 – Gives the Department of Health \$9.2 million to offer the HPV vaccine to girls between 11 and 18.	Passed
Tennessee	House Bill 1517 – Would require the Department of Health to report on the populations by age affected by HPV and report to the legislature with a recommendation concerning the HPV vaccine.	Pending
Texas	House Bill 2220 – Would allow the Executive Commissioner of Health and Human Services Commission to require immunization against HPV for person's admission to elementary or middle school. Senate Bill 110 – Would provide information to parents and would require the HPV vaccine for girls entering 6 th grade. House Bill 1379 – Requires the Department of Health to develop and distribute education materials.	Pending Pending Passed
Utah	House Bill 358 – Establishes an awareness campaign on the causes, prevention, and risks of	Passed

	cervical cancer.	
Vermont	House Bill 256 – Requires all female students entering the 6 th grade to receive the HPV vaccine. Allows parents to opt out.	Pending
Virginia	Senate Bill 722 – Would remove the requirement or girls to receive vaccine for school attendance. Senate Bill 1230 – Requires the HPV vaccine for girls entering 6 th grade.	Pending Passed
Washington	House Bill 1802 – Provides all parents of 6 th graders with information on HPV and where they can get the vaccine.	Passed
West Virginia	House Bill 2835 – Would require the HPV vaccine for girls entering the 6 th grade. Allows for exemptions.	Pending
Wisconsin	Senate Bill 252 – Would require schools to provide HPV information.	Failed
Wyoming	No proposed legislation.	

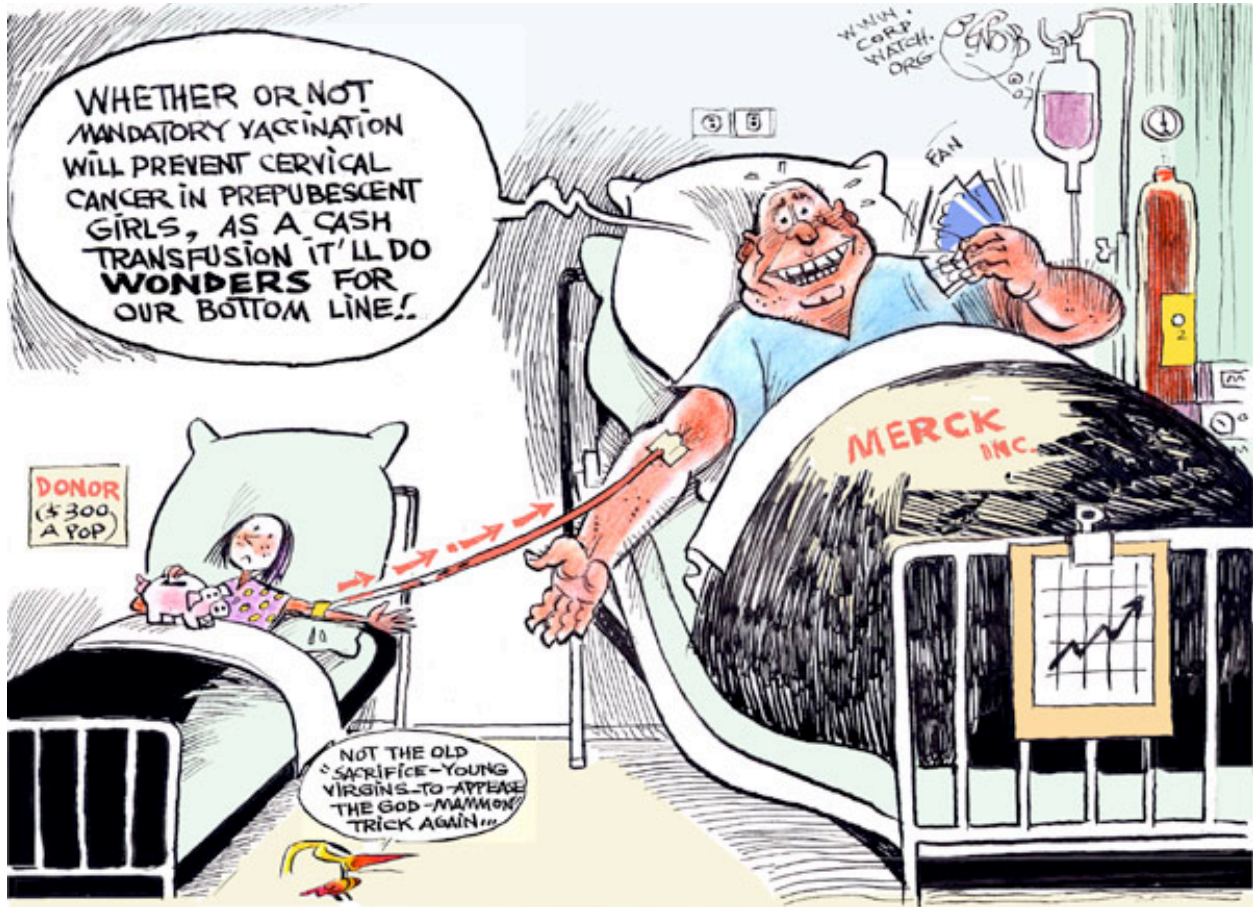
Source: Data compiled from National Conference of State Legislators. Retrieved September

18, 2009, from

<http://www.ncsl.org/IssuesResearch/Health/HPVVaccineStateLegislation/tabid?14381?Default.aspx>

Appendix B

Political Cartoon Depicting Merck's Greed



Source: Picture by Khalil Bendib. No copyright information provided. Retrieved October 4, 2009, from <http://www.corpwatch.org/article.php?id=14401>

Appendix C

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States 2009 For those who fall behind or start late, see the catch-up schedule

Vaccine	Age	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹		HepB	HepB	HepB ^{see footnote 1}	HepB							
Rotavirus ²				RV	RV	RV ²						
Diphtheria, Tetanus, Pertussis ³				DTaP	DTaP	DTaP ^{see footnote 3}		DTaP				DTaP
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	Hib ⁴		Hib				
Pneumococcal ⁵				PCV	PCV	PCV		PCV			PPSV	
Inactivated Poliovirus				IPV	IPV			IPV				IPV
Influenza ⁶							Influenza (Yearly)					
Measles, Mumps, Rubella ⁷							MMR			see footnote 7		MMR
Varicella ⁸							Varicella			see footnote 8		Varicella
Hepatitis A ⁹							HepA (2 doses)					HepA Series
Meningococcal ¹⁰												MCV

Range of recommended ages
Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed vaccines, as of December 1, 2008, for children aged 0 through 6 years. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of

the series. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations, including high-risk conditions: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Hepatitis B vaccine (HepB). (Minimum age: birth)

At birth:

administered at age 1 or 2 months. The final dose should be administered no earlier than age 24 weeks.

4-month dose:

medical conditions (see *MMWR* implant).

6. Influenza vaccine. (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])

medical conditions that predispose them to influenza complications) aged 2 through 49 years, either LAIV or TIV may be used.

Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.

7. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)

dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.

8. Varicella vaccine. (Minimum age: 12 months)

elapsed since the first dose.

at least 28 days after the first dose, it can be accepted as valid.

9. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Administer 2 doses at least 6 months apart.

subsequent visits.

where vaccination programs target older children or who are at increased risk of infection. See *MMWR* 2006;55(No. RR-7).

10. Meningococcal vaccine. (Minimum age: 2 years for meningococcal conjugate vaccine [MCV] and for meningococcal polysaccharide vaccine [MPSV])

component deficiency, anatomic or functional asplenia, and certain other high-risk groups. See *MMWR* 2005;54(No. RR-7).

2. Rotavirus vaccine (RV). (Minimum age: 6 weeks)

14 weeks 6 days. Vaccination should not be initiated for infants aged 15 weeks or older (i.e., 15 weeks 0 days or older).

is administered at ages 2 and 4 months, a dose at 6 months is not indicated.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). (Minimum age: 6 weeks)

at least 6 months have elapsed since the third dose.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib). (Minimum age: 6 weeks)

2 and 4 months, a dose at age 6 months is not indicated.

but can be used as the final dose in children aged 12 months or older.

5. Pneumococcal vaccine. (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])

Source: CDC website. Retrieved September 30, 2009, from http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2009/09_0-6yrs_schedule_pr.pdf

Appendix D

Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States 2009 For those who fall behind or start late, see the schedule below and the catch-up schedule

Vaccine	Age	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis ¹		<i>see footnote 1</i>	Tdap	Tdap
Human Papillomavirus ²		<i>see footnote 2</i>	HPV (3 doses)	HPV Series
Meningococcal ³		MCV	MCV	MCV
Influenza ⁴		Influenza (Yearly)		
Pneumococcal ⁵		PPSV		
Hepatitis A ⁶		HepA Series		
Hepatitis B ⁷		HepB Series		
Inactivated Poliovirus ⁸		IPV Series		
Measles, Mumps, Rubella ⁹		MMR Series		
Varicella ¹⁰		Varicella Series		

Range of recommended ages

Catch-up immunization

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed vaccines, as of December 1, 2008, for children aged 7 through 18 years. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of

the series. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations, including high-risk conditions: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). (Minimum age: 10 years for BOOSTRIX[®] and 11 years for ADACEL[®])

recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoid (Td) booster dose. should receive a dose.

used as a booster dose; however, a shorter interval may be used if pertussis immunity is needed.

2. Human papillomavirus vaccine (HPV). (Minimum age: 9 years)

third dose 6 months after the first dose (at least 24 weeks after the first dose).

previously vaccinated.

3. Meningococcal conjugate vaccine (MCV).

not previously vaccinated.

a dormitory.

terminal complement component deficiency, anatomic or functional asplenia, and certain other groups at high risk. See *MMWR*

remain at increased risk for meningococcal disease should be

4. Influenza vaccine.

underlying medical conditions that predispose them to influenza complications) aged 2 through 49 years, either LAIV or TIV may be used.

younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.

5. Pneumococcal polysaccharide vaccine (PPSV).

(see *MMWR*)

A single revaccination should be administered to children with functional or anatomic asplenia or other immunocompromising

6. Hepatitis A vaccine (HepA).

areas where vaccination programs target older children or who are at increased risk of infection. See *MMWR*

7. Hepatitis B vaccine (HepB).

A 2-dose series (separated by at least 4 months) of adult formulation

8. Inactivated poliovirus vaccine (IPV).

For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.

4 doses should be administered, regardless of the child's current age.

9. Measles, mumps, and rubella vaccine (MMR).

for those who have received only 1 dose, with at least 28 days between doses.

10. Varicella vaccine.

(see *MMWR*)

vaccinated or the second dose if they have received only 1 dose.

administered at least 28 days after the first dose, it can be accepted as valid.

between doses is 28 days.

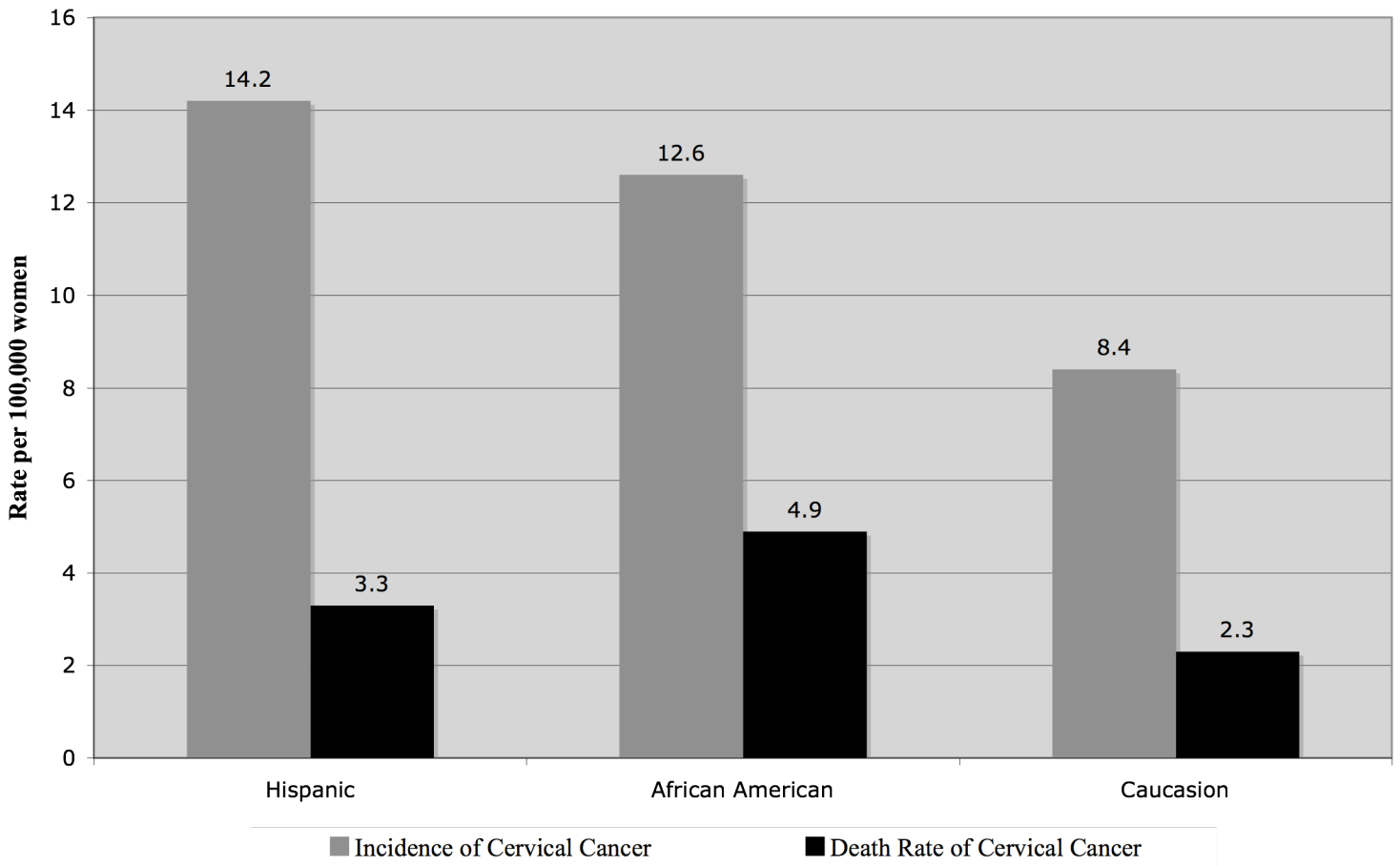
The Recommended Immunization Schedules for Persons Aged 0 Through 18 Years are approved by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>).
Department of Health and Human Services Centers for Disease Control and Prevention

Source: CDC website. Retrieved September 30, 2009, from

http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2009/09_7-18yrs_schedule_pr.pdf

Appendix E

Incidence and Deaths Rates of Cervical Cancer by Ethnicity in the United States, 1998-2003



Source: Data compiled from the CDC website. Retrieved September 30, 2009, from

<http://www.cdc.gov/cancer/hpv/statistics/cervical.htm>

HPV (HUMAN PAPILLOMAVIRUS) VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States.

There are about 40 types of HPV. About 20 million people in the U.S. are infected, and about 6.2 million more get infected each year. HPV is spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV is important mainly because it can cause **cervical cancer** in women. Every year in the U.S. about 10,000 women get cervical cancer and 3,700 die from it. It is the 2nd leading cause of cancer deaths among women around the world.

HPV is also associated with several less common types of cancer in both men and women. It can also cause genital warts and warts in the upper respiratory tract.

More than 50% of sexually active men and women are infected with HPV at sometime in their lives.

There is no treatment for HPV infection, but the conditions it causes can be treated.

2 HPV Vaccine - Why get vaccinated?

HPV vaccine is an inactivated (not live) vaccine which protects against 4 major types of HPV.

These include 2 types that cause about 70% of cervical cancer and 2 types that cause about 90% of genital warts. **HPV vaccine can prevent most genital warts and most cases of cervical cancer.**

Protection from HPV vaccine is expected to be long-lasting. But vaccinated women still need cervical cancer screening because the vaccine does not protect against all HPV types that cause cervical cancer.

3 Who should get HPV vaccine and when?

Routine Vaccination

- HPV vaccine is routinely recommended for girls **11-12 years of age**. Doctors may give it to girls as young as 9 years.

Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact – because they have not been exposed to HPV. For these girls, the vaccine can prevent almost 100% of disease caused by the 4 types of HPV targeted by the vaccine.

However, if a girl or woman is already infected with a type of HPV, the vaccine will not prevent disease from that type.

Catch-Up Vaccination

- The vaccine is also recommended for girls and women **13-26 years of age** who did not receive it when they were younger.

HPV vaccine is given as a 3-dose series:

- 1st Dose: Now
- 2nd Dose: 2 months after Dose 1
- 3rd Dose: 6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

4 Some girls or women should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening **allergic reaction to yeast**, to **any other component of HPV vaccine**, or to a **previous dose of HPV vaccine** should not get the vaccine. Tell your doctor if the person getting the vaccine has any severe allergies.

HPV Vaccine

2/2/2007

- **Pregnant women** should not get the vaccine. The vaccine appears to be safe for both the mother and the unborn baby, but it is still being studied. Receiving HPV vaccine when pregnant is **not** a reason to consider terminating the pregnancy. Women who are breast feeding may safely get the vaccine.

Any woman who learns that she was pregnant when she got HPV vaccine is encouraged to call the **HPV vaccine in pregnancy registry** at 800-986-8999.

Information from this registry will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when the shot is scheduled can still get HPV vaccine. People with **moderate or severe illnesses** should wait until they recover.

5 What are the risks from HPV vaccine?

HPV vaccine does not appear to cause any serious side effects.

However, a vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of **any** vaccine causing serious harm, or death, is extremely small.

Several **mild problems** may occur with HPV vaccine:

- Pain at the injection site (about 8 people in 10)
- Redness or swelling at the injection site (about 1 person in 4)
- Mild fever (100°F) (about 1 person in 10)
- Itching at the injection site (about 1 person in 30)
- Moderate fever (102°F) (about 1 person in 65)

These symptoms do not last long and go away on their own.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Like all vaccines, HPV vaccine will continue to be monitored for unusual or severe problems.

6 What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 How can I learn more?

- Ask your doctor or nurse. They can show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit CDC's website at www.cdc.gov/vaccines.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
Human Papillomavirus (HPV) Vaccine

2/2/07

Source: CDC website. Retrieved September 30, 2009, from

<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv.pdf>