The Power to Choose?

Consequences of the HPV Vaccine Controversy

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ABSTRACT

The human papillomavirus (HPV) vaccine debuted in June of 2006 as a tool for preventing the onset of cervical cancer. Since then, it has been transformed into a vaccine that is said to promote promiscuity and pre-marital sex, infringe upon parental rights to monitor their children's behavior and choices, and unjustly create huge profits for the pharmaceutical industry. Through an analysis of existing literature on HPV, vaccination, public health measures, sexuality, and the sociology of pharmaceuticals, this paper identifies the specific issues that have acted together to politicize the use of the HPV vaccine. The paper concludes that intersecting institutions, societal values, and political practices—above all, the premature push to mandate the vaccine— have worked together to create a controversy so intense that it has been constructed as a social problem. The sociopolitical context of the vaccine has influenced its uptake and how much power and agency individuals really have in choosing whether or not to be vaccinated.

INTRODUCTION

"We chose to help protect ourselves against cervical cancer and other HPV diseases. Now the choice is yours," a fashionable adolescent girl adorned with iPod headphones exclaims on the front page of the Gardasil® website. While she tells website visitors how to download Gardasil screensavers and iron-on t-shirt designs, two other older girls, a mother, and an eleven-year-old talk about the Gardasil vaccine and its importance in cervical cancer prevention. Merck & Co., Inc., the maker of the Gardasil vaccine, has spent the last several years urging consumers to exercise their "power to choose" and get vaccinated against HPV, the virus which can cause cervical cancer in women.

However, Merck's messages of empowerment— delivered passionately to a target audience of young girls and other women—are subdued by the social and political context of the vaccine. As Casper and Carpenter (2008) found, "Containment technologies like the HPV vaccine may prevent infection, but they do not contain politics" (895). The vaccine has ignited a fierce controversy, implicating women and men, children and adults, doctors and patients, public health officials and policy makers, drug companies and insurance companies, the religious right and the feminist left. The HPV vaccine, less than a milliliter of fluid administered three times to girls and young women, is rife with political charge and social controversy. This paper will address the question, how was the vaccine transformed from a medical technology into a divisive sociopolitical issue? Furthermore, what are the consequences of the politicization of the vaccine for the girls and women for whom it was invented? Through a sociological

analysis of existing literature on HPV, vaccination, public health measures, sexuality, and the sociology of pharmaceuticals, this paper identifies the specific issues that have acted together to politicize the use of the HPV vaccine and construct a social problem out of an immunization. I have also analyzed newspaper articles, federal documents, pharmaceutical company materials, Supreme Court cases about vaccination, and consumer health journals to frame the controversy in terms of its social and political context. In this paper, the politics associated with the HPV vaccine have been broken down into three categories: issues that are historically associated with vaccination, issues that are specific to the nature of the vaccine, and issues that are specific to how the vaccine was implemented. An analysis of the effects of the controversy follows.

While this topic is certainly timely and contemporarily relevant, the newness of the issue has posed some notable challenges for this study. Firstly, mandate legislation changes weekly, and monitoring changes in legislation has been a formidable task. Secondly, new medical information about the safety (and dangers) of the vaccine is released almost every day, and not all of the information is included in this analysis. Lastly, because of different approval processes and health care financing systems, this study has been limited to the United States. The analysis in this paper is intended to add to the greater body of knowledge on the relationship between matters of health and politics and the importance of considering the social context of future medical technologies. By turning Merck's empowering claim that you—the consumer—have "the power to choose" on its head and determining who among the various stakeholders has

the most influence on whether or not girls should be vaccinated, we can ask the question: who *really* has the power to choose?

A CANCER VACCINE?

Alex Azar, the U.S. Department of Health and Human Services, declared June 8, 2006 “an important day for public health and for women’s health” (Food and Drug Administration 2006). This day marked the Food and Drug Administration (FDA) approval of Gardasil, the first-ever vaccine said to prevent the development of four types of human papillomavirus (HPV) in females. HPV is the most prevalent sexually transmitted infection in the United States, affecting more than half of sexually active people (Food and Drug Administration 2006). While most of the 40 types of HPV are fought off by the immune system and are asymptomatic, some types of HPV are responsible for causing cervical cancer in women (Centers for Disease Control 2008). About 99.7 percent of cervical cancer is HPV-related and can appear long after the HPV infection has been transmitted (Farrell and Rome 2007). HPV is untreatable, and only the serious health problems caused by the virus can be treated (NCSL 2008). In the United States alone, about 10,000 women get cervical cancer each year, and about 3,700 die from the disease (Centers for Disease Control 2008). Cervical cancer incidence rates are higher in African-American and Latina populations (Scarinci, Garcia-Palacio, and Partridge 2007). This number is small, compared to other countries, some of which do not have widespread use of cervical cancer screening (NCSL 2008). Globally, half a million women develop cervical cancer annually—and half of these women do not

survive, making cervical cancer the second leading cause of cancer deaths in women everywhere (World Health Organization 2007; Centers for Disease Control 2008).

The prospect of a vaccine that can actually protect against HPV— and thus prevent the onset of cervical cancer— sounds promising and, as Azar said, is a milestone development in women's health. While no "magic bullet," the HPV vaccine can potentially reduce the prevalence of cervical cancer by huge proportions (World Health Organization 2007). Gardasil protects against four types of HPV, two of which (types 16 and 18) cause about 70 percent of cervical cancers, and an additional two (types 6 and 11) cause about 90 percent of genital warts (Food and Drug Administration 2006). The vaccine is given at three intervals over a period of six months and costs about $360 in the private sector. As of this writing, in the United States Gardasil has been approved for only females, aged nine through 26 (Centers for Disease Control 2008). Because the vaccine is effective in preventing HPV types 16 and 18 in girls and women who have not yet been infected by these particular types of the virus, the target population for vaccination has been middle school girls. This group is unlikely to have been exposed to the cancer-causing virus, which is transmitted through sexual activity (Kim and Goldie 2008).

The vaccine was generally met with enthusiasm in the scientific and medical community upon its approval. Dr. Andrew von Eschenbach, the Acting Commissioner of Food and Drugs at the time of FDA's approval of Gardasil, called the development of this vaccine "a product of extraordinary work by scientists as well as by FDA's review teams to help facilitate the development of very novel vaccines to address unmet medical

needs" (Food and Drug Administration 2006). Among the winners of the 2008 Nobel Prize for Medicine was the German virologist Harald zur Hausen, whose discovery of HPV led to the development of the vaccine (Altman 2008). The FDA is in the process of approving a second HPV vaccine, marketed as Cervarix by GlaxoSmithKline, for the two types of HPV (types 16 and 18) that cause the majority of cervical cancers (Food and Drug Administration 2006).

In clinical trials, the Gardasil vaccine was 100 percent effective in preventing infection by the two main cancer-causing types of HPV (World Health Organization 2007). Nevertheless, Kim and Goldie (2008) predict that the effect of HPV vaccination on cervical cancer rates will not be clear for decades. The excitement surrounding the HPV vaccine subsided once the novelty of the new medical technology wore off. Evaluating the medical efficacy of the vaccine has fallen in importance as politics has laid claim to the HPV vaccination. As Charo (2007) says, "Cancer prevention has fallen victim to the culture wars" (1905).

The HPV vaccine raises "the spectre of both past controversies about vaccination and current political concerns in the area of sexual morality" (Williams, Gabe, and Davis 2008: 817). Some of the politics surrounding the vaccine have illuminated issues historically associated with vaccination, such as the power of the state to dictate to parents which medical treatments their children must undergo, the rights of children, and the value of achieving what is called "herd immunity." Pushed by the political agenda of the pharmaceutical companies and abetted by the FDA's rapid approval and the CDC's unanimous recommendation of the vaccine, the controversy surrounding the HPV

vaccine has also brought to life issues of power and influence not seen with the introduction of other vaccines. Some of these issues are specific to the nature of the vaccine, while others are a result of when, how, why, and where the vaccine has been introduced and implemented.

The vaccine to prevent HPV is inherently different than most of its vaccine predecessors. Because the vaccine treats a sexually transmitted virus rather than a more casually transmissible infection, unique questions about the urgency and necessity of the vaccination have been raised. The distinction between HPV, which is sexually transmitted, and cervical cancer, which results from HPV and is thus indirectly caused by sexual activity, has been lost in the debate over whether or not the vaccine alters the sexual behavior of adolescents. Unlike other vaccines that are given to both boys and girls without distinction, the HPV vaccine is currently approved for only females in the United States, raising concerns about control over women's bodies and the constitutionality of requiring a vaccine for only one sex. The vaccine is also very costly, which can inhibit the ideals of access and equality.

The political reaction to the vaccine is also due in large part to *how* the vaccine was approved, advertised, and implemented from a policy standpoint. In general, "opposition to HPV vaccine had been muted prior to the controversies stimulated by mandate legislation" (Haber, Malow, and Zimet 2007: 327). The conflicts over the Gardasil vaccine vary from the hasty FDA approval, to the even hastier CDC recommendation; from Merck's successful advertising campaign, to the pharmaceutical company's questionable involvement in lobbying for the vaccine to be compulsory. There

was a rush to mandate the vaccine not long after it was approved, prompting critics to suspect the profit-driven motives of the policy makers. Additional criticisms arose when the HPV vaccine was added to the list of mandatory immunizations for legal immigrants to the United States.

JUST ANOTHER SHOT

Vaccination is considered the most significant public health advance in history. It is the only medical technology that has successfully eradicated diseases (Ulmer and Liu 2002). Through vaccination, once deadly contagious diseases like smallpox have been eliminated from the world's population. The underbelly of successful vaccination is that when diseases are largely eliminated, people don't see the devastation caused by them—and thus they do not realize the objective importance of vaccines. Highly contagious diseases that have been eradicated "have a way of receding swiftly from the popular consciousness to the point where they become completely forgotten" (Chase 1982: 468). When people do not see and experience what they are being vaccinated against, many individuals begin to object to mandatory immunization. In this way, many vaccines "have become victims of their own success" (Ulmer and Liu 2002: 293). Nevertheless, vaccination is usually the default choice for parents, and not vaccinating is considered a deviation from the norm (Hobson-West 2007).

Most of the objections against vaccinations are against the *mandates* that states impose to protect public health. Although mandatory vaccination is an effective public health strategy in cases involving highly contagious, deadly diseases, "imposing mandatory health requirements in situations of low epidemiological risk unnecessarily

constrains individual interests and can undermine the effectiveness of public health activities" (Salmon et al 2005: 780). This is the case with the HPV vaccine; because several state legislators promptly tried to pass bills mandating the vaccine for middle school girls without giving the public time to understand the vaccine and the virus it is said to prevent, a great deal of antagonism arose—controversy that became associated with the vaccine itself, rather than just the mandates. The controversy surrounding the HPV vaccine has uncovered problems with the "lack of consistent clear standards for development of immunization policy" (Haber et al. 2007: 329).

Mandatory vaccination laws in the United States began at the beginning of the nineteenth century after Edward Jenner had developed a vaccine for smallpox in 1796 and the fear of the disease was widespread (Javitt, Berkowitz, and Gostin 2008). The ideal of herd immunity, "in which the protective effect of vaccines extends beyond the vaccinated individual to others in the population," is the impetus for most compulsory vaccination programs (Javitt et al. 2008: 388). When a substantial proportion of a population is immune to a disease, there is less potential for spread of the disease and a greater possibility of its eradication. Opposition to HPV vaccination "represents another chapter in the history of resistance to vaccination and, on some levels, reflects a growing trend toward parental refusal of a variety of vaccines based on the (erroneous) perception that many vaccines are more risky than the diseases they prevent" (Charo 2007).

For vaccination programs to be successful, individuals must willingly submit to vaccination or it must be coerced (Diekema and Marcuse 1998). The method of coercion has historically been requiring immunization for school attendance, dating back to 1827,

when Boston became the first American city to require all children entering public schools to be vaccinated (Javitt et al. 2008). Mandatory school vaccinations have historically been "optimal for rapid and widespread disease protection that is distributed among children regardless of race/ethnicity or socioeconomic status" (Vamos, McDermott, and Daley 2008: 306). In the absence of a largely vaccine-compliant population, mandated vaccination for school attendance guarantees population-wide coverage that would not otherwise exist.

Compulsory vaccination highlights important ethical questions about the conflicting interests of the government, charged with protecting the health of citizens, and of the individuals supposedly being protected, who generally reserve the right to determine which medical treatments are best for themselves and their children. Diekema and Marcuse (1998) refer to John Stuart Mill's "On Liberty" to justify coercive vaccination:

> "'The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant… The only part of the conduct of anyone for which he is amenable to society is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign'" (qtd. in Diekema and Marcuse 1998: 43).

The sovereignty of individuals is difficult to balance with public health measures like vaccination; there is a fine line when exercising power over individuals for the common good. In times when epidemic diseases are not visibly harmful to a population and vaccination is precautionary rather than of absolute necessity, justifying coercion on the basis of preventing harm to others becomes disputable.

In the 1905 case of *Jacobsen v. Massachusetts*, the Supreme Court issued a 7-2 decision that upheld states' rights in passing laws that require children to be vaccinated before entering school. Justice John Marshall Harlan declared that it was within the "police powers" of state and local governments "to guard the community's health, welfare, safety, and morals" (Colgrove and Bayer 2005: 572). However, in order for this to be true, the benefits of protection and herd immunity must outweigh the ever-present risk of invading individual and parental autonomy. Haber et al. (2007) question "whether the benefits of protection against HPV infection warrant the government imposing requirements that supersede parental authority" (326). Because the vaccine is currently only approved for females in the United States, it is considered an "incomplete" vaccine—that is, herd immunity cannot develop unless enough of the population is vaccinated, which certainly cannot occur if only half of the potential carriers of the virus are eligible for vaccination (DeSoto 2007). The lack of justification to mandate the HPV vaccine based on herd immunity is complicated by the non-casual transmissibility of the virus. To what degree an unvaccinated person puts others at risk for HPV will not be determined for years and, "in the absence of potential harm to a third party, such [mandatory vaccination] laws may be considered unacceptably paternalistic" (Colgrove 2006: 2390).

Although critics tend to point to vaccine mandates as being a violation of parents' rights to make decisions about their children's bodies, the rights of children also need to be taken into consideration. With existing vaccinations, children who have been exempted from required immunization are at far greater risk of getting communicable

diseases than those who have been vaccinated. In the face of parental objections, minors have the right to be immunized against illnesses which can be prevented through vaccination, and "society has an interest in safeguarding the welfare of children who may be harmed by the choices of their parents or guardians" (Colgrove 2006: 2390). A parent's decision to not vaccinate his or her child does not only affect the individual child—the health of a community may also be threatened by an abundance of unvaccinated individuals. Ethical analysts have said that it is "the duty of parents to have their children vaccinated in order to prevent harm to others in the community within which they live and from which they derive many other benefits" (Diekema and Marcuse 1998: 41). This debate highlights the classic public health struggle of protecting individual and parental rights, while simultaneously exerting state authority for the common good.

Financial considerations of the impact of disease and the promise of vaccination also need to be considered. The potential for an individual to harm others by the "imposition of financial burdens on the public purse" has made coercion an acceptable means of achieving high vaccination rates (Colgrove and Bayer 2005: 574). HPV and the illnesses it is associated with "exact an enormous financial toll on the health care system" which could be reduced by the coverage and protection achieved through mandated vaccination (Dempsey and Freed 2008: 306). It is still unclear if, in the absence of a mandate, those most at risk for contracting HPV and developing cervical cancer will have access to the vaccine. Individuals who do not have access to routine cervical cancer screening would benefit the most from the vaccine, including a high percentage of

Hispanic adolescents, people living in rural areas, and individuals with low socioeconomic status (Brewer and Fazekas 2007). If the vaccine does not reach these high-risk populations, then the vaccine's promise of reducing the burden of cervical cancer will remain unfulfilled.

Because the target group for the HPV vaccine is early adolescent girls, the rights of the vaccinees are questionable. Although they are children under the law, eleven- and twelve-year-old girls may still have the wherewithal to make the decision to be vaccinated or not. The law dictates that children are not autonomous; because they legally lack agency, they therefore do not have the power to choose whether or not to be vaccinated against HPV. Determining whether or not individuals are competent enough to make the decision to get the HPV vaccine "can be particularly challenging with regard to adolescents, because of individual variations in developmental maturity" (Field and Caplan 2008: 114). If parents do not vaccinate their daughters on moral grounds, they might be denying them protection they could have otherwise had. Issues of religion in conjunction with adolescent sexuality have been dominant in the debate over HPV vaccination, but the push to require HPV vaccination "raises broad questions about the acceptability of mandatory public health measures, the scope of parental autonomy, and the role of political advocacy in determining how preventive health measures are implemented" (Colgrove 2006: 2391).

In general, parents in the United States think of the vaccine as a positive development, and studies show that many parents want their daughters to be vaccinated (Brewer and Fazekas 2007). But must the state intervene in situations where the parents'

personal beliefs cannot be reconciled with the best interest of the child? Many interest groups have raised the matter of parental consent in regards to adolescents and the HPV vaccine. In general, issues "that pertain to adolescents' ability to consent for reproductive health care in an independent fashion and confidential manner already provoke challenging ethical and legal dilemmas" (Farrell and Rome 2007: 434). Many sexual health matters are excluded from parental consent laws in some states, allowing minor adolescents access to such reproductive health services as contraception, education, and pregnancy termination services. There is discussion about including the HPV vaccine in the list of services adolescents can get without parental consent. Since adolescents can consent to *treatment* for sexually transmitted infections, some adolescent medicine specialists believe they should also be allowed to consent to *prevention* via vaccination (Farrell and Rome 2007).

Because HPV is sexually transmitted, some critics view cervical cancer as a result of personal behavior and therefore not a public health problem; the transmission of HPV can simply cease through abstinence and faithfulness. However, this attitude that HPV and cervical cancer are personal problems ignores the interconnectedness of individuals and denies the impending sexuality of adolescents. Furthermore, HPV can be transmitted even to people who have had only one sexual partner, if her partner has himself had other partners. Abstinence and faithfulness do not guarantee protection against HPV (Centers for Disease Control and Prevention). Moral and religious opposition to HPV vaccine mandates is based on an "inchoate concern" that "to recognize the reality of teenage sexual activity is implicitly to endorse it" (Charo 2007). Of course, individuals are

ultimately responsible for their diseases, because they are the ones who have to cope with the consequences. Nevertheless, argues Peter Lewis Allen (2000) in his book *The Wages of Sin*, "institutions under whose auspices we organize and carry out our inner and outer lives—especially religious institutions and government—bear a great deal of responsibility as well… powerful people have felt free to view disease as an agent of God's wrath that punishes sexual behavior considered immoral, and hence to blame the sick for their own sufferings" (159). The moral authority associated with condemning premarital sexual activity, especially of adolescents, has a huge bearing on the perception and acceptance of preventative measures such as the HPV vaccine.

The politics surrounding the HPV vaccine come partially from the anti-vaccine frenzy that has developed in recent years, and the HPV vaccine is just another vaccine to rally against. For many parents, acceptance of the HPV vaccine is dependent on their acceptance of vaccines in general (Lenselink et al. 2007). Anti-vaccine advocates have used the controversy of the vaccine and Merck's involvement in lobbying for a mandate to try to achieve their own reform measures (Alexander 2008). In the past two decades, "in the face of a sharp increase in the number of recommended pediatric vaccines, unproven theories alleging connections between vaccines and illnesses, including autism, diabetes, and multiple sclerosis have been spreading" (Colgrove 2006: 2390). It is ironic that implementing vaccination programs has become more difficult as vaccinations have successfully eliminated diseases. As a result, "public attention has shifted from the risks of the disease to the risks of vaccination" (Salmon et al. 2005: 778). The anti-vaccine activists have in recent years formed a social movement, built around safety concerns of

vaccinating children and attacks on mandatory vaccination (Colgrove 2006). Specifically with the HPV vaccine, questions of vaccine safety have partially been stimulated by "the rapidity with which mandate legislation was initiated" (Haber et al. 2007: 329). The public backlash to the suggestion of mandating the vaccine was unprecedented in vaccine history.

A VACCINE LIKE NO OTHER

The Advisory Committee on Immunization Practices (ACIP)—the only federal governmental agency that makes written recommendations for the routine immunization of children and adults—recommends routine vaccination of girls aged 11 and 12, although the agency says the HPV vaccination series can begin as early as age nine (Centers for Disease Control and Prevention). The issue of gender has raised questions about the constitutionality of requiring a vaccine that is only approved for females—when, ostensibly, the vaccine may in the future be approved for males in the United States. Although women are the only ones who can obviously suffer from cervical cancer, men, too, are carriers of the cancer-causing virus. While the vaccine has not yet been approved for males in the United States, it has been approved for males and females alike in Australia, Mexico, and some European nations (Hoffman 2008). Vaccinating young males as well as young females would more effectively achieve herd immunity than only targeting females (Haber et al. 2007).

Most vaccines are administered during childhood, the HPV vaccine being no exception. Objections to vaccination in general notwithstanding, the issue of age in the HPV vaccine controversy is significant only at its intersection with the gendered nature

of the vaccine and the sexually transmitted virus it is said to prevent. The ACIP recommends the vaccine for eleven- and twelve-year-olds not only because girls in this age range are unlikely to be sexually active yet, but also because younger adolescents are more likely to benefit from the higher antibody titers (Centers for Disease Control 2007). While all vaccines are surrounded by the "politics of contagion and containment," because the HPV virus is sexually transmitted rather than casually communicable it "provokes longstanding controversies swirling around sex, gender, and women's bodies in the US" (Casper and Carpenter 2008: 896). The approval of Gardasil for only females has raised questions that arose in the Victorian age in England, when there was a movement to protect men from women infected with sexually transmitted diseases (Griffiths 2007).

The criticism of the vaccine has created an atmosphere of contention, between those who believe that the vaccine is medically and morally dangerous, and those who consider the vaccine a miraculous breakthrough in women's health and cervical cancer prevention. The claims-making by family values groups that the vaccine poses a threat to sexual innocence and safety has helped to construct a social issue out of the controversy. According to Macionis (2005), social issues are "political debates involving moral judgments about how people should live" (21-2). The controversy is largely on moral, ethical, and political grounds, rather than on objective medical facts. Williams, Gabe, and Davis (2008) say that "it is not so much the public debates about vaccination as such that are the most important dimensions to the story here, but that its target is a sexually-transmitted disease, which thereby draws into the debate issues of sex, gender and

women's bodies that are far more charged" (817). Although some groups have targeted the questionable long-term effectiveness of the vaccine and the safety of the vaccine itself, most of the opposition to the vaccine and the proposed mandates centers around subjective notions of female sexuality, abstinence, and interference with the rights of individuals and parents. Despite the moral outcry, parents' opinions of the vaccine are based more on safety issues rather than the risk of promoting promiscuity, suggesting that there is a "disjuncture between moral conservatives and American parents overall" (Casper and Carpenter 2008: 895).

The HPV vaccine holds a unique position in the history of school immunization requirements. School mandates are generally reserved for infectious diseases transmitted via casual contact. Two vaccines, against Hepatitis B and Tetanus, prevent infections that are not casually communicable (Haber et al. 2007). In 1981, the vaccine against Hepatitis B, a virus that is mostly (but not exclusively) transmitted via sexual activity, was introduced. Despite expectations that the Hepatitis B vaccine would ignite controversy, it was not widely contested; likely, the vaccine escaped heated criticism because Hepatitis B is not purely sexually transmitted and the vaccine is administered to younger children, "when the spectres of puberty and sexual activity are less haunting" (Casper and Carpenter 2008: 896). The tetanus vaccine is administered as part of the DTaP (diphtheria, tetanus, and pertussis) series, although tetanus is not a communicable infection. However, the seriousness of a tetanus infection and its administration with vaccines that do prevent communicable diseases warrants it being compulsory for school children (Haber et al. 2007).

Although the Gardasil vaccine effectively protects against certain types of HPV, it is no magic bullet. There are a lot of unknowns about the vaccine that will only be deciphered over time. Researchers do not know how long immunity to the HPV types prevented by the vaccine will last, or whether or not a booster shot will be needed (Centers for Disease Control 2007). Clinical trials have not been conducted over extended periods of time, and although the FDA has approved of the general safety of the vaccine, further studies need to be done to determine the long-term safety and efficacy of the vaccine (Centers for Disease Control 2007).

INTRODUCING & IMPLEMENTING THE VACCINE

Hastily approved by the FDA, recommended within weeks for all middle school girls by the CDC, and pushed by state legislatures to be put on the list of mandatory vaccinations, Gardasil entered public consciousness thunderously. Meanwhile, the media has been bombarding television viewers and magazine readers with Merck's empowering advertising and the idea that by getting the vaccine, girls can be "one less" with cervical cancer. There are many barriers to the acceptability of the vaccine, including the misunderstood link between HPV and cervical cancer, concerns about cost, and concerns about the safety of the vaccine (Scarinci et al. 2007). The push to mandate the HPV vaccine without public discourse "caught many persons off guard and seemed to stimulate a great deal of alarm" (Haber et al. 2007: 329). Additionally, voluntary measures were not taken or attempted before mandates were suggested and introduced. It all happened quickly—too quickly. The controversy surrounding legislation to make the vaccine mandatory spread rapidly, "and the intensity of the criticism has distracted from

the fact that this vaccine represents a significant breakthrough for women's health" (Haber et al. 2007: 325). Government organizations are not alone in their unanimous recommendation of the HPV vaccine; the main medical associations also supported the ACIP's recommendations for eleven- and twelve-year-olds to receive the vaccination (Casper and Carpenter 2008).

Since Gardasil was approved in 2006, legislators in 41 states and the District of Columbia have introduced HPV vaccine legislation, in the form of either mandated vaccination for school attendance, mandated insurance coverage or state funding, public education about the vaccine, or the establishment of committees to make policy recommendations about the vaccine (Javitt et al 2008). In September of 2006, Michigan was the first state to introduce legislation pertaining to the HPV vaccination (Casper and Carpenter 2008). By May of 2007, there were 24 states, and the District of Columbia, which had introduced bills to make the HPV vaccination mandatory—yet only two states have passed laws (Casper and Carpenter 2008). Both Virginia and the District of Columbia have passed and implemented legislation requiring girls entering sixth grade to receive the vaccine; however, parents can refuse the vaccine— in Virginia after reviewing materials about the link between HPV and cervical cancer, and in Washington through a handful of opt-out provisions (Javitt et al. 2008).

There was a huge conservative moral and political backlash against mandating the vaccine. The Arizona legislature passed a bill which preemptively prohibited the health department from mandating the vaccine (Casper and Carpenter 2008). In February 2007, Governor Rick Perry of Texas issued an executive order that the HPV vaccine be

required for girls entering middle school. The state legislature overruled the governor's order, but not until after news spread that Merck had been lobbying legislators for the vaccine to be mandated and was a contributor to Governor Perry's re-election campaign. Merck also contributed money to the group Women in Government, which supports routine use of the vaccine (Haber et al. 2007). The conflation of politics with the pharmaceutical industry raises broader questions about the conflicts of interests between profit-driven industry and political organizations, which claim to have the best interest of patients in mind.

The exorbitant cost of the HPV vaccine—around $360 for the full course—has also been a subject of controversy. Prior to the FDA approval of Gardasil, Zimet et al. (2000) found that the cost of the vaccine would be a major factor in consumer acceptability. The vaccine's cost inhibits its uptake internationally; "to date [the vaccines] are only available in industrialized countries and have yet to become accessible to poorer countries where the greatest burden of disease exists" (Andrus et al. 2008: L81). Because the vaccine has not been licensed for a long period of time in the United States, many insurance companies have not rushed to cover it, even though early studies showed that the vaccine would likely be cost-effective and a good use of health care resources (Haber et al. 2007; Goldie et al. 2004).

The price tag of the vaccine has been linked to potential mandates because vaccines that are mandated for school attendance must be affordable and accessible. While older vaccines have been historically affordable and have saved health care systems money by preventing diseases that take a toll on the country's economy, any

mandatory HPV vaccination program will be expensive to execute. Even under federal vaccine contract, the HPV vaccine costs $96.75 for each of the three doses (Vetter and Geller 2007). Policy makers quickly attempted to mandate the vaccine, without due consideration of the limited supply and the cost of vaccinating every eleven to twelve-year-old girl in America. Nationwide mandates, without proper planning, may "place economic burdens on federal and state governments and individual practitioners and may have a negative impact on the provision of other health services" (Javitt et al. 2008: 385).

On the other hand, vaccine mandates can "trigger several mechanisms that promote universal access" and "can alleviate disparities in access" (Field and Caplan 2008: 117). Support for mandates comes from groups like Women in Government, which wants to ensure the vaccine is affordable and accessible to everybody, following in the tradition of breast cancer activists who "have mobilized through many political channels to combat an illness that disproportionately burdens women" (Colgrove 2006: 2390). The idea that mandating a vaccine for the purpose of making it financially feasible for everyone illuminates the entanglement of the health care system with politics. Furthermore, if HPV vaccine uptake is impeded by "existing disparities in health care access and use, the vaccines may widen rather than narrow existing disparities in cervical cancer deaths" (Brewer and Fazekas 2007: 113).

The debate over Gardasil has been extremely public in the United States. The media has given a great deal of attention to HPV vaccine mandates, which "has given anti-vaccine groups and other groups who have specific issues with a STI [sexually transmitted infection] vaccine a platform to broadcast their criticism of HPV vaccination"

(Haber et al. 2007: 327). While feminist groups "heralded the vaccine as a pharmaceutical lifesaver," mandates were attacked by moral conservatives, parental rights groups, and those opposed to vaccination in general (Casper and Carpenter 2008: 894). Conservative groups such as Family Research Council and Focus on the Family initially condemned the HPV vaccine itself because of the widespread belief of the religious right that vaccinating young girls against a sexually transmitted virus would promote promiscuity and destroy their message of abstinence. However, after Merck countered this claim with evidence that the vaccine did not appear to have such an effect on sexual behavior because of other more prominent risk factors of sexual activity, family values groups redirected their focus to vaccine mandates (Casper and Carpenter 2008).

Seeking to "regain the upper hand in the sex wars by shifting the terms of the debate from *providing* the vaccine (acceptable) to *mandating* the vaccine (unacceptable)," conservative groups such as Family Research Council expressed support for the vaccine (Casper and Carpenter 2008: 895). Religious groups, like Focus on the Family, opposed a mandate because an HPV vaccine mandate represents "an attempt by the secular state to force a child to undergo an intervention that may be irreconcilable with her family's religious values and beliefs" (Colgrove 2006: 2389). The real issue is not the Gardasil vaccine; rather, it is the underlying sexual politics that have found an outlet in the vaccine and the accompanying fear of a mandate.

Before the release of the HPV vaccine, emphasis on the vaccine's role in cancer prevention was predicted to be a key factor in acceptability of the vaccine (Zimet et al. 2000). Hoping that cervical cancer is less likely to stir up controversy than its sexually

transmitted origin, Merck has made substantial efforts to market the vaccine as a cancer vaccine rather than an HPV vaccine. The cover of one patient pamphlet distributed by Merck to doctors' offices says, "You'd tell her she has lipstick on her teeth. So why wouldn't you tell her about a virus that can cause cancer?" (Merck 2006). Merck has spent many years and large quantities of money trying to portray HPV as a virus that can be prevented by vaccination. Critics of the vaccine have brought to light the indirect relationship between the Gardasil vaccine and cervical cancer—the vaccine protects against particular types of HPV, two of which can cause cervical cancer. The link between HPV and cervical cancer, and what role the vaccine plays, is not made clear to the public. According to studies on public knowledge of HPV, "there is a good deal of misunderstanding about HPV infection, cervical cancer screening, and the sequelae of HPV infection" (Zimet 2005: 517).

The media had been disseminating information about the HPV vaccine for years before Gardasil was approved, and the media portrayal of the vaccine continues to influence its public perception (Calloway et al. 2006). The attempt to market the vaccine in "culturally-palatable ways" may "diminish the controversy associated with it, but whether such a diminution will occur over time remains an empirical question" (Casper and Carpenter 2008: 896). Rather than diminishing, the controversy over the vaccine has escalated. New concerns about the vaccine are constantly arising. Adding to the controversy surrounding the mandate, as of July 1, 2008, immigrants in the vaccine's target group wishing to become legal permanent residents must be vaccinated against HPV (U.S. Citizenship & Immigration Services 2008).

THE EFFECTS OF THE CONTROVERSY

Although there was initially an enthusiastic response to the vaccine, "the availability of an HPV vaccine will not change the course of cervical cancer in this country unless there is widespread demand by and access for the targeted populations" (Vetter and Geller 2007: 1262). Merck realized early on the need for the public to demand the vaccine. Gardasil was the first vaccine to be marketed directly to consumers and, from even before the vaccine was approved, "Merck took the lead in shaping how education and information about HPV and the vaccine was reaching women," beginning years before FDA approval of Gardasil with their "Tell Someone" campaign, which "taught potential female consumers that cervical cancer is caused by HPV" (Alexander 2008). Merck continued their forceful marketing after Gardasil was approved, marketing the vaccine aggressively to the consumers who were earlier encouraged to "tell someone" and are now being urged to "become 'One Less' in the fight against cervical cancer" (Alexander 2008).

The debate over the Gardasil vaccine has shaped public opinion and contributed to widespread confusion about the vaccine itself. Accurate, comprehensive, and unambiguous information—if it exists—has been overshadowed by the social construction of a "problem of the HPV vaccine" rather than the "promise of the HPV vaccine." According to Casper and Carpenter (2008), "Epistemological and practical confusion surrounding CC [cervical cancer] and HPV, and the vaccine targeting them, contribute to political struggles that are sexualised and gendered. These struggles are consequential for perceptions and use of the vaccine, and for the social worlds in which it

is deployed" (896). The virus and the vaccine to prevent it have become political tools. Even before the vaccine was available, the religious right used HPV as part of its abstinence-only message because HPV can still be transmitted with condom usage (Alexander 2008). The risks associated with HPV gave abstinence-advocates a further opportunity to demonstrate that abstinence until marriage is the only foolproof way to avoid contracting a sexually transmitted infection. The virus has been exploited to send a cultural message—both by the religious right and those who think the vaccine is the greatest modern development in women's and public health. The expectations and conflicting reality of the vaccine demonstrate the power pharmaceuticals have over consumers. The development of new vaccines generates "hopes, fears, and a variety of other moral and political agendas which both hark back to the past and project into the future" (Williams et al. 2008: 820).

Producers of pharmaceuticals play a significant role in constructing the social reality of any type of medical technology. Given their immense influence and wealth, pharmaceutical companies both in the United States and abroad have the power "to use their ideological, economic and political power to play on the anxieties and discontents of life in late modern society creating a market for their products that extends well beyond obvious health needs" (Busfield 2006: 310). In the case of the HPV vaccine, Merck (and GlaxoSmithKline, should Cervarix be approved by the FDA) stands to profit tremendously from widespread use of the vaccine. A mandate is certainly in the best interest of Merck, who has used its enormity and power to influence vaccine policy. An important lesson from the controversy over HPV vaccination is that "open, transparent,

and thoughtful discussion of relevant issues, including the tension between public health directives and parental autonomy, needs to take place well before mandate legislation is proposed" (Haber et al. 2007: 329). The rush to require the vaccine, as supported by Merck, policy makers, and state legislators, has become the thorn in the heel of the movement.

CONCLUSION

In this paper, I have addressed the social forces, institutions, and values that have worked together to transform the HPV vaccine from a medical technology into a controversial sociopolitical issue, and the consequences that have transpired as a result of this controversy. As this paper has demonstrated, the politics of the HPV vaccine stem mostly from the premature push by states to mandate the vaccine for girls entering middle school. The determination to make the HPV vaccine compulsory has politicized the use of the vaccine itself and has created a controversy that inhibits rational discussion about whether or not the vaccine can help those it is intended to help. In order to evaluate the merits of the vaccine—to have a "*bona fide* clinical discussion"—it is "essential to sort out the science from external political and media influences" (Godfrey 2007: 1397). Unfortunately, a clinical discussion of the vaccine has been impeded by the heated politics surrounding it.

Mandatory public health measures can be justified ethically only if "voluntary measures have failed, no less coercive alternatives exist, the scientific rationale is compelling, and members of the general public are unknowingly at risk" (Lo 2007: 357). The implementation of the HPV vaccine did not adhere to these ethical guidelines; rather,

mandates were proposed only months after the FDA had approved Gardasil, before enough information about the safety and efficacy has been gathered and disseminated and before a public discourse on the vaccine and the HPV virus could transpire. What resulted from this impulsive move to mandate the vaccine was an impassioned debate over individual rights, adolescent sexuality, the corrupt motives of pharmaceutical companies, and family values.

A social issue has been constructed out of the controversy surrounding the vaccine, affecting all of the stakeholders involved—public health officials, parents, physicians, the pharmaceutical industry, the payers and, of course, patients. Public health officials face the risk of the backlash against the HPV vaccine having consequences for other vaccines. Pushing for mandates may not only "undermine the goal of widespread HPV vaccine coverage" but also has the potential to "lead to public distrust of established childhood vaccine programs for other diseases" (Javitt et al. 2008: 385). Parents have been at the center of the mandate debate, having to address issues of their children's sexuality and health without due notice and information. Physicians and health practitioners, who ultimately are the ones who administer the vaccine, are constrained by the misleading public perceptions of the vaccine. The pharmaceutical industry has been attacked for its aggressive marketing of the vaccine—without proper regard to the fact that it was the government's Food and Drug Administration that hastily approved the vaccine and it was government officials who were the public faces of lobbies to mandate the vaccine. Payers, including insurance companies and federal agencies like the Vaccines for Children program, must cover the vaccine if it is mandated. Because of the

unparalleled cost of the vaccine, covering it may entail withholding funding for other health initiatives in the United States, and may be impossible in developing countries. Cervical cancer is especially epidemic in countries with low resources, particularly in the northernmost nations of South America and in eastern Africa (Schiffman and Castle 2005). Of the 273,000 deaths caused annually by cervical cancer, 80 percent are women in developing countries—demonstrating the unfortunate connection between cervical cancer and poverty (Andrus et al. 2008). Future studies should examine the impact of the HPV vaccine controversy in developing countries, where cervical cancer is a far greater problem than it is here in the United States.

Lastly, patients are the ones most impacted by the controversy. While policymakers, feminist organizations, religious groups, and medical associations battle over whether or not Gardasil should be mandatory, young girls are wrongly being told that they have the power to choose to be vaccinated. Adult women who are eligible for the vaccine have more agency, certainly, than their younger counterparts, but their power is also restrained by the social context of the vaccine. The HPV vaccine is a prime example of how a medical technology can be exploited as a lens through which to address pertinent social and political issues. The politics surrounding the vaccine—the vaccine's social context— has taken on a life of its own, undoubtedly conditioning the patient's power to choose.

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