MANDATORY HPV VACCINATION: 
IS THERE A HAPPY MEDIUM?

BY ILENE ALBALA*

“We chose to help protect ourselves against cervical cancer and other HPV diseases. Now the choice is yours.”

When most people think of vaccinations, they often associate them with mandatory compliance, but this quote from Merck’s innovative advertising strategy epitomizes the company’s focus on personal choice. Merck & Co., a global pharmaceutical company and maker of a number of vaccines, including Gardasil® for the human papillomavirus (HPV), has implemented consumer-driven advertising to an extent previously unknown in vaccine marketing. Given the increasing opposition to vaccines, and the controversial issues surrounding HPV, Merck’s approach to this vaccination campaign is very clever. Some call it a revolutionary public health campaign; and others call it greedy consumer capitalism—really, it is a bit of both.

Merck stands to earn $2 to $4 billion if states require mandatory HPV vaccinations and Gardasil® is administered to young women across the country, yet the company spent twenty years developing the vaccine. Merck’s aggressive advertising campaign includes a website that allows visitors to send e-cards, create screensavers, design t-shirts, and add a banner to their blogs, all advocating HPV vaccination. The t-shirts, buddy icons, and screensavers all advocate their message of personal choice—they all simply state—“I Chose.” Even insulating sleeves at Starbucks warn of the dangers of cervical cancer.

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1 For more information on the economics of cost and pharmaceutical research and development, see John A. Vernon, Examining the Link Between Price Regulation and Pharmaceutical R&D Investment, 14 Health Economics 1 (2005); see also Sigrid Fry-Revere, The Rush to Vaccinate, N.Y. Times, Mar. 25, 2007.


3 Id.
The vaccine developer has also sought to influence states through the use of various lobbying techniques. Some would argue that the lobbying has the purpose and effect of unfairly biasing state legislatures. However, it is important to recognize that few women even knew about HPV; thus Merck has had to convince consumers and states that HPV is a real problem. Indeed, HPV is a real problem—it is the most common sexually transmitted infection and it causes cervical cancer. However, the very fact that the virus is spread through sexual contact causes angst for parents and pro-abstinence groups. Add growing anti-vaccination sentiment to the mix, and the result is Merck's need for an innovative advertising and lobbying strategy.

While Merck's focus on advertising personal choice is a smart move for the company, the company's ultimate goal is to persuade states to make the vaccination mandatory. Should states continue to allow the HPV vaccine to be a matter of personal choice, or is this something that all school-aged girls should be required to receive? While the issues surrounding HPV vaccination are complex, the benefits of vaccination are clear: protecting women from cervical cancer. Mandatory school-based vaccination would be ideal for dramatically reducing the spread of cancer-causing HPV. However, cost concerns and fear that HPV vaccinations will lead to increased promiscuity impede the vaccine's success, and must be combated in order to achieve the ultimate goal of eliminating most cervical cancers. In this paper, I address the issues surrounding school-based mandatory HPV vaccination. In Section I, I will briefly discuss the growing anti-vaccination trend in the United States. In Section II, I will describe HPV and the vaccine. In Section III, I will discuss the legal authority supporting vaccinations. In Section IV, I will describe state legislation dealing with HPV vaccination—in particular, I will look at Virginia and Texas, states that have taken initially aggressive action.

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4 See Jasmin A. Tiro, Helen I. Meissner, Sarah Kobrin & Veronica Chollette, What Do Women in the U.S. Know Human Papillomavirus and Cervical Cancer?, 16(2) CANCER EPIDEMIOLOGICAL BIOMARKERS PREV. 288 (2007); see also Eva Yacob & al., University Students' Knowledge and Awareness of HPV, 28 PREVENTIVE MEDICINE 535 (1999).

5 Lauri E. Markowitz et al., Center for Disease Control, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices, 56 MORBIDITY AND MORTALITY WEEKLY REPORT EARLY RELEASE 1 (Mar. 23, 2007).
towards mandating the vaccine. In Section V, I will address the unique set of issues associated with the HPV vaccine. Section VI will address issues related to cost and limited resources. Ultimately, in Section VII, I conclude that while mandatory school-based vaccination against HPV is the ideal solution, the most practical solution may be to follow Virginia’s most recent proposal, mandating that all health insurance cover the vaccine. Proposing mandatory vaccination, along with appropriating funds to local health departments to provide the HPV vaccine to girls who are ineligible for the federally-funded Vaccines for Children Program and who are not expected to receive the vaccine from private health insurance, would allow for the greatest access to the vaccine, without ignoring the issues surrounding the vaccine.

I. THE ANTI-VACCINATION MOVEMENT

While Merck’s direct-to-consumer advertising strategies may be new, advertising campaigns to influence vaccination are not. Beginning in the 1920s, public health officials sought to “sell” the public on the importance of vaccination. These campaigns utilized a range of emotions to appeal to consumers, including guilt and fear. One radio broadcast spot decades ago appealed to parents’ fear of harming their children: “If your child comes down with polio, measles, diphtheria, or mumps, it’s probably your fault, because your child was not properly immunized.” Ironically, this type of emotional appeal is now exploited by anti-vaccination groups. One such anti-vaccination website employed this tactic: “This lovable, extremely alert baby had never produced such a blood-curdling scream as she did at the moment the shot was given...four hours later, Lee Ann was dead.” This type of rhetoric is hard for public health officials and vaccine

developers alike to combat. Instead of using the same tactic of emotional appeal, Merck’s aggressive advertising strategy hinges on personal choice.

The fundamental conflict underlying a mandatory vaccination policy is that between personal choice and collective safety. While the state has the authority to compel vaccination, there are also medical and non-medical exemptions from vaccination requirements offered in nearly every state. The rate of non-medical exemptions is increasing, and children who become ill are contributing to outbreaks of preventable diseases.9 Not only are the unvaccinated children themselves at risk of getting diseases vaccines would have prevented them from contracting, but these children also risk transmitting these diseases to susceptible populations (including the elderly, neonates, and those with compromised immune systems).10 Nonetheless, the percentages of non-medical exemptions among school-age children continue to grow. In Michigan, in the 2003–2004 school year, 5.7% of children in school were exempted from vaccination. Michigan is not alone—six other states reported exemption rates of 3% or higher as well.11 Unvaccinated children are also reported in clusters, increasing the possibility of an outbreak.12

10 Id. at 470.
12 Clustering can occur, for example, if the members of a religious community, living in an isolated geographic area, decide not to vaccinate their children. One study illustrated the “paradoxical result of herd immunity” which is that “more cases [of measles] were reported from the group of vaccine-accepting individuals [in such a community] than from those who decline vaccination for other than religious reasons [but] who live among vaccinated individuals. It has been observed before in the United States...that staying in an area with low vaccine coverage is the most important risk factor for vaccinated children to contract measles,” Id. at 471. See Susan van den Hof, Marina A. E. Conyn-van Spaensock & Jim E. van Steenbergen, Measles Epidemic in the Netherlands, 1999-2000, 186 J. INFECTIOUS DISEASES 1483, 1485 (2002); see also, Daniel R. Feikin, Dennis C. Lezotte & Richard F. Hamman, Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization, 284 J. AM. MED. ASS’N 3145, 3148.
The most common reason for refusing to vaccinate a child is concern over the vaccine’s safety.13 One study found that parents of unvaccinated children were much less likely than other parents to trust the government and less likely to report confidence in medical, public health, and government sources for vaccine information, but more likely to trust alternative medicine professionals.14

Anti-vaccination websites appeal to their audience by questioning the scientific veracity of vaccination, arguing that vaccinations are not safe for children, and by alleging collusion between doctors, pharmaceutical companies, and the government.15 These websites can also appear legitimate—one in four anti-vaccination websites purports an implied official status at a national or international level.16 The majority of these websites listed extensive references, though most were self-published works or sources from alternative medicine.17

While Lee Ann perhaps represents one case of an immunization gone wrong, the numbers indicate that there is much greater collective harm in refraining from vaccination. On average, children who remained unvaccinated due to non-medical exemptions in the United States between 1985 and 1992 were thirty-five times more likely to contract measles than vaccinated children.18 The website for the Vaccine Education Center at the Children’s Hospital Of Philadelphia provides compelling reasons to vaccinate children, including the fact that prior to the wide availability of polio vaccinations, polio paralyzed 10,000 U.S. children each year.19

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13 Salmon, supra note 9, at 470–76.
14 Id. at 470–76.
15 Davies, supra note 8, at 22.
16 Id.
17 Id.
18 Salmon, supra note 9, at 47-53.
19 Children’s Hospital of Pennsylvania Vaccine Education Center,
http://www.chop.edu/consumer/jsp/microsite/microsite.jsp?id=75918 (providing the following facts: “Before vaccines, parents in the United States could expect that every year: polio would paralyze 10,000 children; rubella (German measles) would cause birth defects and mental retardation in as many as 20,000 newborns; measles would infect about 4 million children, killing 3,000; diphtheria would be one of the most common causes of death in school-aged children; a bacterium called Haemophilus influenzae type b (Hib) would cause meningitis in 15,000 children, leaving many with permanent brain damage; and pertussis (whooping cough) would kill thousands of infants”).
Despite these warnings, opposition against vaccination is growing. What the anti-vaccination movement fails to recognize is that the danger to a child in abstaining from vaccination is far greater than in receiving a vaccine.\(^{20}\)

II. **HUMAN PAPILLOMA VIRUS (HPV)**

HPV is not often thought of as a public health threat requiring vaccination. That is due, in part, to the fact that HPV is spread through sexual intercourse.\(^{21}\) Yet HPV is the most common sexually transmitted disease and is the second leading cause of death from cancer worldwide.\(^{22}\) Over 6.2 million people are infected with HPV every year, and there are over twenty million cases in the United States.\(^{23}\) Women have an 80% chance of acquiring HPV by age fifty. One study found that the prevalence of HPV in female teenagers in an urban area is 64%\(^{24}\) and another study found that 26.8% of females aged fourteen to fifty-nine had HPV.\(^{25}\) The numbers indicate that the virus is a public health threat—the chance of getting the virus is incredibly high and certain types of HPV can lead to cervical and other cancers. Over one hundred types of HPV have been identified, forty of which infect the genital area.\(^{26}\) Although the majority of infections subside on their own, with no clinical symptoms, certain

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\(^{21}\) There are studies that suggest that HPV can be spread through nonsexual exposures, as well. See Renato L. Rombaldi et al., *Transplacental Transmission of Human Papillomavirus*, 5 VIROLOGY J. 106 (2008). However, one in-depth study of this phenomenon found “strong” evidence that HPV is “sexually transmitted.” See Susanne Kruger Kjaer et al., *High-Risk Human Papillomavirus is Sexually Transmitted: Evidence from a Follow-Up Study of Virgins Starting Sexual Activity (Intercourse)*, 10 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 101, 105 (2001).


\(^{23}\) Markowitz, *supra* note 5, at 1.

\(^{24}\) Trudee A. Tarkowski et al., *Epidemiology of Human Papillomavirus Infection and Abnormal Cytologic Test Results*, 189 J. INFECTIOUS DISEASES 46, 46-50 (2004).


\(^{26}\) Markowitz, *supra* note 5, at 1.
types of HPV can cause cervical cancer in women. Both men and women can acquire HPV. While only women can get cervical cancer from the virus, men can get genital warts from several strains of HPV (the two most common are types 6 and 11). Although Pap smears (Papanicolaou) have decreased the rate of cervical cancer in the United States, in 2007 alone, over 11,000 new cases of cervical cancer were diagnosed. Thousands of women in the U.S. will die as a result of cervical cancer each year, for example, in 2005, 3,924 women died from the disease.

Gardasil®, the only HPV vaccine currently on the market, was approved by the FDA in June of 2006 for girls and women aged nine to twenty-six. Gardasil® is a non-living, non-infectious, synthetic, recombinant vaccine that stimulates an antibody response that neutralizes the virus. This is not a vaccine against cancer, rather a vaccine against HPV, which causes cancer. In 2003, all of the 11,820 U.S. cases of cervical cancer were attributable to strains of HPV associated with cancer. Cancer-causing HPV types (mainly type 16) have also contributed to 90% of anal cancer and 40% of cancers of the vulva, vagina, and penis. While cervical cancer from HPV takes about ten to twenty years to develop in a woman’s body, the goal of the vaccine is to prevent the two types of HPV (types 16 and 18) from forming lesions, which cause 70% of

27 Id.
28 Id.
29 Id. at 2.
30 Id. (finding the number of cervical cancer deaths to be between 3,000 and 7,000 women each year).
35 Markowitz, supra note 5, at 3.
36 Id.
cervical cancers. Gardasil® also prevents HPV types 6 and 11, which are the cause of approximately 90% of genital warts. In clinical trials, Gardasil® has been found to be 95–100% effective against HPV types 6, 11, 16, and 18.

The FDA recommends the vaccination prior to the start of sexual activity. The reason for the young age of vaccination is that the vaccine is believed to be most effective before a woman’s first exposure to the virus. Since HPV is so common, the best way to ensure prevention among teenage girls and young women is to vaccinate them prior to any sexual activity, ideally when girls are eleven to twelve years old. For the HPV vaccine to be effective, the woman needs three shots total. The second shot is given two months after the first, with the third an additional four months later. More studies are needed to determine whether an additional booster shot will be required. Ongoing studies are testing the vaccine in males, as well.

Soon after the FDA recommended Gardasil®, the vaccine was recommended by the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control (CDC), and the American Cancer Society. The ACIP’s recommendations are considered by individual states that decide whether to propose mandatory school-based vaccination. This federally sponsored committee does not require vaccines; it merely recommends them. The measles, mumps, and rubella vaccine (MMR) is

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37 Women should still be regularly tested, as the HPV vaccine guards against only 70% of cervical-cancer-causing HPV, thus there is still a possibility of getting cervical cancer from HPV caught even after vaccination.
38 Markowitz, supra note 5, at 6.
39 John T. Schiller et al., An Update of Prophylactic Human Papillomavirus L1 Virus-like Particle Vaccine Clinical Trial Results, 265 VACCINE K53-K61, K55 (2008).
40 National Public Radio, supra note 34; Markowitz, supra note 5, at 5.
41 National Public Radio. supra note 34.
43 Complicating matters even further have been the unexpected consequences of the ACIP’s recommendation for HPV vaccination, namely that federal immigration authorities now require immunization against HPV for female immigrants ages 11 to 26 who are seeking permanent residence. This requirement, mandating that all immigrants receive vaccinations that are recommended by the ACIP, comes from the Immigration and Nationality Act, last amended by Congress in 1996. Some view this as an additional barrier to immigration, others view this as hypocritical and wonder why we require female immigrants to get the HPV
an example of a vaccine which has been recommended by the ACIP, and which is now required in every state.

III. **LEGAL AUTHORITY TO VACCINATE**

The legal authority to vaccinate falls under the police power of the state. The legislature may empower the state board of health to prescribe any method of vaccination, so long as it is not arbitrary. Over a century ago, the United States Supreme Court in *Jacobson v. Commonwealth of Massachusetts* recognized the authority of the state “to enact quarantine laws and ‘health laws of every description,’” finding that “[t]he safety and the health of the people of Massachusetts are, in the first instance, for that commonwealth to guard and protect. They are matters that do not ordinarily concern the national government.”\(^{44}\) Thus, the Court found that the authority to vaccinate lies within the state’s police powers, which include reasonable regulations enacted by the legislatures in order to protect “public health and public safety.”\(^{45}\) In dicta, the Court explained that as long as the enacted police power does not contravene the Constitution, or infringe any right it grants, the state has the power to act. In *Jacobson*, an opinion seldom challenged and widely followed, the Court found that mandatory vaccination is a reasonable measure taken by the state to ensure public health and safety.\(^{46}\) The Court held that an adult who is medically “fit” for vaccination is included under mandatory vaccination laws, and thus must pay a fine according to the statute if he or she does not abide by the vaccination requirement. In highlighting the tension between personal freedom and public health, Justice John Marshall Harlan, writing for the Court, underscores the importance of collective safety:

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vaccine, but not other young women in the U.S.


\(^{45}\) *Id.* at 25.

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. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.47

In 1922, the Court then extended Jacobson to children, overriding parental authority, by upholding an ordinance requiring school-based vaccination.48 While some may claim that the state’s authority to compel vaccination depends on the infectious nature of the health threat, tetanus is an example of a required vaccine that does not protect against an infectious illness. HPV falls somewhere in between—the virus is infectious, but only by sexual transmission. This mode of transmission adds an element of choice, and thus controversy, arguably absent in other infectious diseases requiring vaccination.

One of the main reasons why the public health arena is able to invade individual autonomy in the case of vaccination is because it has proven effective in eradicating disease. In 1970, a natural vaccination experiment took place in the town of Texarkana.49 The town is located on the border of Texas, where the measles vaccination was not required, and Arkansas, where the vaccination was required. An epidemic of measles

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broke out, and the rate of infection in Texas was twelve times higher than in Arkansas. Texas mandated vaccination for school attendance shortly after the epidemic.

Mandatory vaccination, more so than many other public health endeavors, represents a fundamental tension between individual rights and rights of the society as a whole. For this reason, states have carved out exemptions from state mandated vaccination laws. Every state can exempt people who have a medical condition that makes them unfit for vaccination.\(^{50}\) All but two states allow exemptions for religious reasons, and about half the states allow exemptions for “reasons of conscience.”\(^{51}\) Proposed legislation for HPV vaccination allows for non-medical exemptions, including “reasons of conscience” exemptions.

However, recent scares of bio-terrorism led to the creation of an act that potentially stretches state police power to a breaking point. The Model State Emergency Health Powers Act (MSEHPA) includes a provision that those who refuse to comply with mandatory vaccination could be charged with a misdemeanor and subjected to immediate isolation and quarantine.\(^{52}\) One of the MSEHPA’s greatest critics, George Annas, doubts whether Jacobson is still legally viable today, as he argues that over one hundred years later both “medicine and constitutional law are radically different.”\(^{53}\) Annas contends that given the fact that we now allow competent adults the right to refuse medical treatment, perhaps these rights have expanded into the arena of vaccination as well. However, we still permit quarantine of persons with serious communicable diseases if they refuse treatment.\(^{54}\) Given the increase in personal autonomy relating to medical decisions, Annas contends that this model act is more appropriate for the 19\(^{th}\) Century than it is for today. The authors of the act defend their work by insisting that the act contains adequate safeguards for personal liberties. The MSEHPA was recently revised and some of its

\(^{50}\) Id.

\(^{51}\) Hodge, supra note 46, at 863–67.

\(^{52}\) Colgrove, supra note 7, at 242.


most controversial provisions were taken out. Regardless of the controversies over the MSEPHA, *Jacobson* remains good law.

IV. LEGISLATION

As of 2007, twenty-four states have proposed legislation mandating HPV vaccination, though legislatures in Mississippi, West Virginia, Kentucky, and New Mexico have all defeated these types of bills. Virginia has been the most aggressive in requiring HPV vaccination and, in 2007, the Virginia state legislature adopted a law requiring school-based HPV vaccines for girls. The law requires that the first dose of the vaccine be administered to students before they enter the sixth grade.55 In 2008, the Virginia House voted to delay the vaccination requirement until 2010,56 but the Virginia Senate rejected the proposed delay.57 Virginia has also considered whether the vaccine should be covered by insurance providers. In September of 2007, the Virginia House passed a bill mandating local insurance coverage of the HPV vaccine.58 However, in May of 2008, a Special Advisory Commission on Mandated Health Insurance Benefits voted not to recommend the mandate requiring coverage of the HPV vaccine. The main reason for not recommending the mandate was that existing widespread coverage of the HPV vaccine made statewide coverage appear imprudent.59 No other HPV mandate was proposed in Virginia during the 2008 Session.60

55 Va. Code Ann. § 32.1-46 (West 2007) (requiring “[t]hree doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade.”).
57 Senate Panel Rejects HPV Vaccinations Delay. ASSOCIATED PRESS, Feb. 21, 2008.
60 Id.
Texas’s initial steps towards mandating the vaccine were more controversial and ultimately unsuccessful. On February 2, 2007, Texas Governor Rick Perry issued an Executive Order requiring the HPV vaccine for girls prior to admittance to the sixth grade.\textsuperscript{61} However, Representative Dennis Bonnen subsequently proposed House Bill 1098, which essentially defeated the order. As amended at one point, Bill 1098 stated that “[a]ny executive order by the governor imposing a requirement for a person’s immunization against human papilloma virus before admission to any elementary or secondary school is void.”\textsuperscript{62} In response to the negative reaction of the legislature, Governor Perry rescinded his Executive Order. Thus, Virginia remains the only state to mandate a school-based HPV vaccine requirement.

V. UNIQUE ISSUES WITH HPV

Since HPV is a sexually transmitted virus, the vaccine raises a unique set of issues. One of the biggest arguments against making the HPV vaccine mandatory is fear of an increase in adolescent promiscuity.\textsuperscript{63} Critics of mandating the vaccine argue that HPV, unlike other infectious diseases for which vaccination is already mandated, is transmitted almost exclusively via sexual contact, and thus can be avoided. Since there is an element of choice involved in acquiring HPV, critics contend that the vaccine should be optional. The argument is that because the virus is sexually transmitted, girls and women can opt to not have sex, and thus not be exposed to the virus. Therefore, since there is an element of choice in acquiring HPV, the critics contend that we should not make the vaccine

\textsuperscript{61} 32 Tex. Reg. 599 (Feb. 16, 2007).
mandatory. However, this argument underestimates the prevalence of sexual conduct among teens, and does not address the fact that not all sex is voluntary.

Parents and pro-abstinence groups also fear that young girls will become more promiscuous because the vaccine will give them a false sense of protection against sexually transmitted diseases. In a survey given to the parents of eleven- and twelve-year olds, parents believed that the HPV vaccine would nearly double the number of sexual partners their child had in their lifetime. However, there is no evidence to support this fear of increased promiscuity.

The Hepatitis B vaccine was also met with controversy because it protected against a disease that was transmitted through sexual contact and intravenous drug use. Michael Belkin, a parent who blames the Hepatitis B vaccine for the death of his daughter, testified before Congress in an attempt to have the forty-two states requiring the vaccine rescind their policies, arguing: “Almost every newborn U.S. baby is now greeted on its entry into the world by a vaccine injection against a sexually transmitted disease for which the baby is now at risk because they [public health officials] couldn’t get the junkies, prostitutes, homosexuals, and promiscuous heterosexuals to take the vaccine.” Yet unlike HPV, which is primarily spread through sexual contact, Hepatitis B can also be acquired by children under age five from unknown sources. This distinction is crucial to some who argue against mandatory vaccination for HPV because first, abstinence is the best prevention, and second, the vaccine may lead to increased promiscuity.

For those concerned with the consequence of promoting sexual activity, framing HPV as a vaccine against cancer makes the vaccine much more palatable. While pro-abstinence advocacy groups fear that vaccina-

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65 Basu, *supra* note 63, at 19018 (finding the mean increase in expected promiscuity to be 1.8 with a 95% Confidence Interval of 1.6–1.9).
66 *Id.*
68 *Id.*
ting adolescents will make them more promiscuous, thinking of the vaccine solely as a prevention of cancer assuages some of its perceived moral complexity. One such group is Concerned Women for America, which aims to “bring Bible principles into all levels of public policy.”

The executive vice president of the group, Wendy Wright, says that she initially thought the vaccine “would seem to send a message that we’re expecting the girls to be sexually active.” However, now that she understands that the vaccine’s main purpose is to protect against cervical cancer, Wright feels more comfortable with it. Wright is comforted by the idea that even women who remain abstinent until marriage may benefit from the vaccine as it will prevent them from contracting the virus if their husbands did not abstain.

Public health education is the best way to combat these unfounded fears of increased promiscuity. Pro-abstinence groups and activists are not the only ones concerned with the sexual consequences of this vaccine; as noted above, parents of the targeted age group believe that receiving the vaccine would nearly double their child’s number of sexual partners. This type of misunderstanding can be addressed through targeted public health campaigns. Perhaps one of the reasons for this heightened fear in parents is that the targeted age group is preadolescents and young adolescents, who are young but not so young that they will not raise questions about the vaccine. Targeting girls age eleven and twelve makes parents uncomfortable, because their daughters could ask about the vaccine, and parents may feel uncomfortable discussing sexual activity with their fifth grade child. While increasing the age of vaccination to sixteen or seventeen may make parents less concerned about vaccination, there is a reason for vaccinating eleven- and twelve-year-olds.

Targeting girls aged eleven to twelve is the most efficacious and cost-effective way of preventing HPV. Both Gardasil® and Cervarix® (GlaxoSmithKline’s recently developed HPV vaccine, which is not yet

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69 Rubin, supra note 22.
70 Id.
71 Id.
72 Basu, supra note 63, at 19020.
FDA-approved) appear successful in protecting women who do not already have HPV types 16 or 18 from cervical cancer. However, once infected with types 16 or 18, the vaccines do not cause regression of the virus.\textsuperscript{74} Furthermore, Gardasil\textsuperscript{8} does not appear therapeutic in nature, meaning that there was no significant difference found in the rate of progression in women who had pre-existing HPV types 16 or 18 and who were then given the vaccine versus the control group, women with HPV infection who were not vaccinated.\textsuperscript{75} These results indicate that targeting adolescent girls before they engage in sexual activity is the optimal way to ensure the prevention of these types of HPV.

Critics also argue that we do not know much about the HPV vaccine or how long protection against these specific HPV types will last.\textsuperscript{76} However, the vaccine has been tested in over 30,000 girls and women, with five years of post-vaccination monitoring. With FDA approval, the vaccine has now been given to hundreds of thousands of females. Gardasil\textsuperscript{8} proved 98\% effective\textsuperscript{77} in preventing the most definitive cervical cancer precursor in those women who did not have any of the four HPV types vaccinated against prior to vaccination, and who received all three shots.\textsuperscript{78}

In terms of its safety as a vaccine, unlike older vaccines that were composed of the actual virus in small doses, either alive or dead, Gardasil\textsuperscript{8} is a virus-like particle composed of fragments of the HPV L1 protein in yeast cells. Theoretically, this should make the vaccine much safer, and is compared to other virus-like particle vaccines, such as tetanus and Hepatitis B. While vaccinated women tend to experience temporary pain at the injection site, no serious risks are associated with the vaccine.\textsuperscript{79} With 94\% of the adverse events associated with Gardasil\textsuperscript{8} being considered non-serious, according to recent data from the first post-marketing study, the vaccine is considered safe.\textsuperscript{80}

\textsuperscript{74} Schiller, supra note 39, at K57.
\textsuperscript{75} Id.
\textsuperscript{76} National Public Radio, supra note 34.
\textsuperscript{77} Schiller, supra note 39, at K56 (setting the confidence interval at 95\%).
\textsuperscript{78} Id. at K55.
\textsuperscript{79} Id. at K61.
\textsuperscript{80} Note that serious adverse events (including hospitalization, Guillain-Barre Syndrome, or blood clots) normally occur in 10–15\% of major vaccines. See INFORMATION FROM FDA
Critics also argue that, given the vaccine’s recent creation, we do not know how long a vaccination will provide protection against certain HPV types. However, modern vaccine trials are not designed according to a “wait and see” model. Instead, vaccine trials test titer levels in test subjects, which indicate their bodies’ antibody response to the virus following the introduction of the vaccine’s antigen. Testing titer levels is an FDA approved, cost effective model for testing a vaccine’s efficacy. Once the vaccine is FDA approved, then the pharmaceutical company will begin post-marketing surveillance studies.

VI. COST & LIMITED RESOURCES

One of the main arguments against mandating the HPV vaccine pertains to its cost. Administration of Gardasil is expensive—costing between $360 and $540 for the three shots. Indeed, it is the most expensive vaccine ever recommended by the Centers for Disease Control and the Prevention Advisory Committee on Immunization Practices. Mandating the HPV vaccine will likely force insurers to provide coverage so that young women can afford the vaccine. There is also evidence suggesting that targeting adolescent girls is the most cost-effective

82 See generally John T. Schiller et al., An Update of Prophylactic Human Papillomavirus L1 Virus-like Particle Vaccine Clinical Trial Results, 268 VACCINE K53-K61 (2008).
83 See generally Bram Palache, New Vaccine Approaches for Seasonal and Pandemic Influenza, 26 VACCINE 6232, 6233 (2008).
85 See Basu, supra note 63, at 19022 (estimating that the cost of the vaccine itself is $120 per dose x 3 doses; the vaccine administrative costs are $15 per dose x 3 doses; the patient time costs are $20 per visit x 3 visits; and clinician fees to patients are $15 per visit x 3 visits).
86 VA. CODE ANN. § 32.1-46 (West 2007).
approach to preventing the virus.\textsuperscript{87} For those who cannot afford insurance there is the federally sponsored Vaccines for Children (VFC) program, which provides free vaccines to all states’ Medicaid-enrolled children, and some uninsured and underinsured, ages nine to eighteen.\textsuperscript{88} Since Gardasil\textsuperscript{89} has been approved by the Advisory Committee for Immunization Practice, the vaccine will be covered by the VFC, allowing uninsured women access. However, while the VFC covers the vaccine itself, it does not pay for the doctor’s visit and administrative cost, or the implicit travel cost and work-time related expenses for which a parent bringing in a daughter must account. Furthermore, the VFC only provides coverage for a minority of low-income patients, some of whom are unaware that they are eligible for free vaccination.\textsuperscript{90} One study found that the average household would still have to bear $181 of the cost of a complete vaccination.\textsuperscript{90} In order to maintain the VFC budget, the cost of the vaccine itself would also need to be reduced from $120 per dose to $65 per dose.\textsuperscript{91} Current vaccine pricing is based on market valuations, rather than actual budgets and public health need.\textsuperscript{92} These types of studies may help indicate target vaccine pricing to make it more affordable.\textsuperscript{93}

A bill was introduced in the Virginia state legislature in September 2007 that proposed mandating that health insurance benefits cover HPV vaccination.\textsuperscript{94} The bill, House Bill 2877, would require health insurers, health care subscription plans, and health maintenance organizations to provide coverage for HPV vaccination for all girls and women aged nine to twenty-six.\textsuperscript{95} This bill follows separate legislation from 2007 mandating

\textsuperscript{87}Kim, supra note 73, at 830.
\textsuperscript{89}Katie M. Keating et al., Potential Barriers to HPV Vaccine Provision Among Medical Practices in an Area with High Rates of Cervical Cancer, 43 J. ADOLESCENT HEALTH S61, S63 (2007).
\textsuperscript{90}Basu, supra note 63, at 19020.
\textsuperscript{91}Id.
\textsuperscript{92}Basu, supra note 63, at 19021.
\textsuperscript{93}Id.
\textsuperscript{94}VA. CODE ANN. § 32.1-46 (West 2007).
\textsuperscript{95}Id.
that, beginning in October of 2008, incoming sixth grade girls receive the first of three shots of the HPV vaccine. Given the recent trend of insurance providers covering the vaccine, the anticipated additional cost to Virginia’s insured is negligible.96

However, in the evaluation of House Bill 2877, critics contend that if coverage for the vaccine is widely accepted, then a mandate may not be as necessary.97 According to a survey conducted by Virginia’s Bureau of Insurance in 2007, thirty-four insurers in the state of Virginia currently provide, or intend to provide, some level of coverage for the vaccine to women through age twenty-six.98 However, “some level of coverage” could be as little as $2 off of a $540 vaccine. Additionally, 20% of insurers (ten companies) did not respond to the survey, and nine companies indicated that they did not offer coverage options that would be affected by the mandate.99

Even if most major insurers cover the vaccine, without state intervention, there is no guarantee that the vaccine will be accessible to patients. Private insurance coverage only equates to accessibility if health workers are willing to carry the vaccine. However, since the vaccine is expensive, clinics may not be willing to risk stocking the vaccine in large quantities, out of fear that the unused vaccine will result in great financial loss.100

Supporters of mandatory HPV vaccination also contend that even with widespread insurance coverage, mandatory statewide coverage is critical to ensuring that the populations at the highest risk of contracting HPV have access to the vaccine.101 Now more than ever, there is a need for mandating this vaccine so that minority populations will get vaccinated. The results of a recent study by the CDC indicate significant racial disparities in cancer detection time and treatment. On November 15, 2008, the CDC released a report detailing rates of cancer from HPV in

96 Id.
98 Id.
99 Id.
101 Id.
the U.S. between 1998 and 2003.\textsuperscript{102} Findings suggest that black and Hispanic women had higher rates of “unstaged” cervical cancers, indicating that women in these minority groups were more likely to receive less aggressive treatment or no treatment at all.\textsuperscript{103} Another recent study found that only one in four black adolescent women has received the vaccine.\textsuperscript{104} Serious racial disparities associated with HPV suggest strong evidence for nationwide school-mandated HPV vaccination.

In an attempt to reach a “happy medium,” the Virginia General Assembly appropriated $1.4 million to increase public access to the vaccine in 2007. The money would go to local health departments to provide the HPV vaccine to girls who are ineligible for the federally funded Vaccines for Children Program and who are not expected to receive the vaccine from private health insurance.\textsuperscript{105} While $1.4 million is a good start, the Virginia Department of Health (VDH) indicates that if the vaccine were mandated, it would require approximately $12 to $13 million annually to pay for the vaccine. The VDH is trying to find alternative sources of funding, exploring, among other options, requiring those with insurance to pay a small fee (currently, the VDH does not require any payment).\textsuperscript{106}

In defeating the Texas Governor’s executive order mandating the HPV vaccine, Representative Dennis Bonnen contended that he had no issues with girls getting the vaccine, but did have issues with mandatory vaccination. A strong supporter of mandatory HPV vaccination, Representative Jessica Farrar of Texas employed powerful rhetoric contesting Bonnen’s argument against the vaccine. Farrar fears that barring a school-based requirement will deny many girls access to the vaccine as they “do not have regular check-ups with their pediatricians that allow parents to hear about the newest medical advances. They are victims of a broken system that is made up of the haves and the have-nots, and they are on the

\textsuperscript{103} Id. at 2863.
\textsuperscript{104} \textit{Most Young, Black Females are Not Getting HPV Vaccine}, U.S. NEWS & WORLD REPORT, Feb. 4, 2009.
\textsuperscript{105} \textit{Health and Human Resources}, http://hac.state.va.us/documents/2007/Post-Session/HealthHumanResources.pdf.
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losing end."\textsuperscript{107} For Farrar, the issue is more than the sheer cost of the vaccine—it is also about barriers to education. Mandating the vaccine will at least create a dialogue about HPV, but without state enforcement, many girls and their parents will not know to engage in this discussion. This following quote by Farrar addresses her concern that this generation of girls will likely not see statewide vaccination requirements, and some of those girls who do not receive the vaccine will get cervical cancer:

We will have to look into the faces of the girls, by then young women, that would have been subject to the school-based HPV vaccine requirement in our state. By then, I regret to say, some will have developed pre-cancerous cervical cells that require invasive and expensive medical treatment in an effort to stave off cervical cancer...Those young women that were denied access to the vaccine will deserve an answer...\textsuperscript{108}

When those young women with cervical cancer ask why they were denied access to the vaccine, Farrar invites those who opposed legislation to give those girls an answer. “Explain,” she says, “why you saw it fit to get your own daughters and granddaughters vaccinated against HPV through the physicians your private health insurance plan pays for. If they are worth protecting, why aren’t all of the girls of Texas worthy of the same?”\textsuperscript{109}

Yet critics contend that HPV vaccination is a waste of our limited resources. Some consider the anti-HPV campaign trivial and argue that our money should be spent on more pressing health concerns. HPV, however, is not a trivial concern; over 3,000 women will die this year in the U.S. from cervical cancer.\textsuperscript{110} The HPV vaccine is expensive, but we

\textsuperscript{108} Id.
\textsuperscript{109} Id.
already spend $2.9 billion a year on HPV-related screening.\textsuperscript{111} This screening includes Pap smears for women who become infected with one of the types of HPV that potentially leads to cancer. Thus, the cost of the vaccine would be offset by a reduction in the need for follow-up exams and for surgery in people who exhibit precancerous lesions.

With state budgets dwindling in a recession, the issues complicating the HPV vaccine, including cost, could mean benching vaccine legislation altogether. While the issues surrounding HPV vaccination are complicated, we must not forget how simple the aim of the vaccination is: to prevent an infection that causes cervical cancer. The ideal situation would involve school-based mandatory HPV vaccination, with insurers forced to cover the vaccine. However, the cost of such an endeavor may be too great for now. Thus, while states discuss budgeting, a short-term solution is that every state should instead consider implementing Virginia’s recent proposal, which would make the vaccine accessible to a greater percentage of the population, and to those who need it most.

VII. SOLUTION

The ideal solution would be school-based mandatory vaccination against HPV. Requiring the vaccine would compel all young girls to get vaccinated against a virus that can lead to cervical cancer. However, diminishing state budgets and concern from parents over the safety of, efficacy of, and feared increase in promiscuity resulting from the HPV vaccine impede mandatory vaccination attempts. Virginia is currently the leader in mandating HPV vaccination and even it is facing impediments to achieving this goal.

Cost and fear of increased promiscuity are two of the biggest hurdles facing HPV vaccination. As discussed in Part VI, this is the most expensive vaccine the ACIP has ever recommended, costing up to $540 for all three doses needed.\textsuperscript{112} While threats of mandatory coverage have compelled most private insurers to cover all or part of the vaccine, those girls who need it most are left without a solution. The VFC program only

\textsuperscript{111} Basu, supra note 63, at 19021.

\textsuperscript{112} This number includes additional expenses associated with vaccination; the average cost of the three doses alone is $360.
covers a minority of low-income children, and coverage for the vaccine by the manufacturer does not go beyond office-based clinics.\(^{113}\) Yet most low-income families rely on public health clinics for vaccinations and these clinics are not covered by the manufacturer's program. Furthermore, as the most recent CDC report concluded, low-income, minority women have much higher rates of HPV at all stages, and are much less likely to receive adequate screening for cervical cancer.\(^{114}\)

While mandatory school-based HPV vaccination would force most insurers to cover the vaccine, for a significant minority of girls, cost will remain a problem. Virginia’s “happy medium” solution of appropriating $1.4 million to increase public access to the vaccine in 2007 is one temporary method for providing maximum access to the vaccine. The benefit of this solution is that the money would go to local health departments to provide the HPV vaccine to girls who are ineligible for the federally funded Vaccines for Children Program and who are not expected to receive the vaccine from private health insurance.\(^{115}\) Providing money to local public health departments will ensure access to a significant minority of girls and women who are at risk of acquiring HPV types that may lead to cervical cancer. The appropriation of $1.4 million is a good start, though much more funding is necessary to ensure continued access to larger numbers of young girls. Indeed the Virginia Department of Health indicated that should the mandate be implemented, it would require $12–$13 million a year to cover the vaccine. Thus, one proposed solution to deal with this problem is to compel families with insurance who choose to get the vaccine at the local health department to pay a very small fee for the vaccine (currently, they pay nothing). The Virginia Department of Health is wary of charging money to those wanting to be vaccinated, as it wants to avoid competing with the private sector. However, charging a small fee may be the only option to provide affordable, accessible vaccines to the greatest number of people.

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114 *Id.*
Yet even if the vaccine becomes more affordable, parents will still be concerned that the vaccine will result in increased promiscuity. Again, making the vaccine mandatory may force parents to confront this issue head-on and then let them decide if they want to opt-out of vaccination. However, barring mandatory vaccination, educating parents about the vaccine is crucial. With parents fearful that the vaccine may double the number of their child’s sexual partners, the misunderstanding must be clarified; otherwise many parents will be very reluctant to vaccinate their child voluntarily. The problem with public health education is, once again, cost. Who is going to pay for this education? The CDC’s budget is limited, and its approach to HPV education likely will not reach enough of an audience for it to be effective. Thus, we come back full circle to Merck and other vaccine developers. Merck advertises not only for the vaccine, but also about HPV education. Five years ago, not many people had even heard about HPV—they did not realize that it was a potentially serious health threat. However, with Merck’s advertising strategy, many more people now know about HPV, and are asking questions about it. Should we look to Merck to educate parents about their potentially misguided fears of an increase in promiscuity? True, Merck stands to gain a profit by selling the vaccine, but if we do not have the money to educate the public about a health threat, is there such a great harm in allowing Merck to advertise? What is worse, allowing Merck to educate the public about HPV or having no education on the issue at all? I would argue that the former is preferable because at the very least, this could open up a dialogue, whereas the latter leaves us with no conversation to start.

VIII. CONCLUSION

Merck’s aggressive advertising campaign for HPV vaccination raises questions about why such a potent strategy is needed. However, rising anti-vaccination sentiment, unique issues with HPV including fear of increased promiscuity, and high cost all suggest that such an aggressive advertising strategy is necessary. Merck’s campaign may be revolutionary in terms of the extent to which its direct-to-consumer advertising strategy has infiltrated consumers’ daily lives. While advertising campaigns for vaccines are not new, the Gardasil® campaign may be a wake-up call to
public health officials that once again, we need to persuade the public of the importance of vaccination.

Merk even began lobbying states for mandatory school-based vaccination, but following the backlash against Governor Perry’s executive order, the company has since halted lobbying efforts.\textsuperscript{116} While critics argue that the motives behind the campaign are solely monetary, the arguments for a mandatory HPV vaccine are real.

State-mandated vaccination would compel parents to vaccinate their daughters against the virus. At the very least, parents would be urged to start a dialogue about HPV. If, after a discussion about the vaccine, parents choose not to vaccinate their daughters, nearly all the proposed legislation would allow for a parental opt-out clause for “reasons of conscience.” Furthermore, state-mandated, school-based HPV vaccination would ensure coverage of the vaccine by major insurers. If mandated, states would also likely be compelled to find alternative solutions to financing the vaccine, including putting pressure on the vaccine developer to cut the cost of the vaccine.

Thus, mandatory vaccination is the ideal solution. However, with budget cuts and a failing economy, mandatory HPV vaccination is taking a back seat to arguably more pressing health concerns. Furthermore, Merck is no longer lobbying states for compelled vaccination. Insurance companies, however, are still lobbying, and their efforts against requiring the vaccine are significant. A special committee in Virginia’s legislature has recently advised that a proposed bill ensuring insurer coverage of the vaccine was not necessary at this time. The main reason for the committee’s decision was that most private insurers currently provide, or intend to provide, coverage of the vaccine to Virginians. The Committee concluded by saying that it wanted to monitor insurance coverage levels and then reconsider the need for a mandate should insurance companies reduce or eliminate vaccine coverage.\textsuperscript{117}

While Virginia’s temporary solution of appropriating funds to local public health departments would help ensure greater accessibility to those in need of the vaccine, this solution is contingent on major health

insurance companies providing coverage (which will likely be out of fear of a statewide mandate). Thus, perhaps by proposing mandatory coverage, states can provide an incentive to insurance companies to provide some sort of coverage and then supplement this with funding to local health departments. However, unless the statewide mandate appears sincere, insurance companies have no incentive to continue to provide statewide coverage. All states should propose mandatory school-based vaccination, allow insurance companies to react by providing coverage, and then supplement this coverage by appropriating funding to local public health departments. The likely result will be that insurance companies would rather provide coverage without a mandate than be forced into paying for the vaccine. However, even if private insurers cover the vaccine, without state regulation, there is no guarantee of vaccine accessibility. Thus, state legislators need to work with experts to ensure not only that the vaccine is covered, but also that it is available to those who need it.

Merck’s aggressive advertising campaign represents the pinnacle of this complex, emerging public health threat. Issues such as the anti-vaccination trend, fear of promiscuity, cost, and the role of the vaccine developer are all central themes surrounding HPV vaccination. While the goal may be simple—to prevent cervical cancer in women—the solution is multifaceted, requiring extensive funding and improved public education. With Merck’s cessation from lobbying on this subject and our declining economy, we will likely see states suspending their proposed legislation requiring the vaccine. However, in order to make the vaccine affordable and accessible, states must continue to push for mandatory vaccination and, in the meantime, try to supplement access to the vaccine and public health education by appropriating funding to their local health departments.