The Aftermath of the Introduction of the Human Papillomavirus Vaccination

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I. Introduction

When a disease is labeled as sexually transmitted, those who contract it are often stigmatized as promiscuous.¹ This unfortunate label has overshadowed the significance of the Food and Drug Administration's (FDA's) recent approval of the first vaccination for Human Papillomavirus (HPV), the most common sexually transmitted infection in the United States.² Approximately twenty million people are currently infected with HPV.³ Research has indicated that certain “high-risk” types of HPV can cause cervical

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³ Centers for Disease Control (CDC), Fact Sheet: Genital HPV Infection, available at http://www.cdc.gov/std/HPV/hpv.pdf (last visited Nov. 6, 2007) [hereinafter Genital HPV Infection] (providing general information about the virus and its connection to cervical cancer). Statistics show that at least fifty percent of sexually active men and women acquire genital HPV infection at some point in their lives. Id. Almost half of those people infected with HPV are between the ages of fifteen and twenty-five years of age. American Cancer Society (ACS), Cancer Reference Information: Frequently Asked Questions About Human Papillomavirus (HPV) Vaccines, available at http://www.cancer.org/docroot/CRI/content/ CRI_2_6x_FAQ_HPVP Vaccines.asp (last visited Nov. 6, 2007) [hereinafter ACS FAQs].
cancer, the second most common cancer in women worldwide.  

While the public is undoubtedly enthusiastic about the landmark "cancer vaccine," the sexually transmitted nature of HPV has stirred a debate in many states regarding whether the vaccine should be mandatory for teenage girls. 

This note will discuss: 1) the prevalence of HPV among adolescent and adult women in the United States; 2) the connection between HPV infection and cervical cancer; 3) the development and implementation of the HPV vaccine in the U.S. market; 4) state legislative actions in response to the vaccine; and 5) the concerns raised in connection with proposals for a mandatory HPV vaccine. After providing background information on the causes, symptoms, and prevalence of HPV and the HPV

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4 See FDA Press Release, supra note 2; see also National Cancer Institute (NCI), Study Estimates Overall HPV Prevalence in U.S. Women, adapted from 4 NCI CANCER BULL. 10, Mar. 6, 2007, available at http://www.cancer.gov/cancertopics/hpv-prevalence0307 (reporting findings from a 2007 National Health and Nutrition Examination Survey) [hereinafter NCI Study]; see also ACS FAQs, supra note 3 (explaining way different HPVs are grouped). Each HPV virus is given a number, referred to as the HPV type. ACS FAQs, supra note 3. Because some HPV types cause warts they are called human papilloma viruses. Id. A papilloma is a type of wart that is a non-cancerous tumor. Id. "The papilloma viruses are attracted to and can only survive in squamous epithelial cells in the body." Id. "Squamous epithelial cells are thin, flat cells that are found on the surface of the skin, cervix, vagina, anus, vulva, head of the penis, mouth, and throat." Id. HPVs cannot thrive in other parts of the body. Id. About sixty types of HPV cause the most common types of warts, those located on non-genital skin, such as on the hands and feet. Id. The other forty or so HPV types, however, are mucosal. Id. "Mucosal" refers to the body's mucous membrane, or the moist skin-like layers that line organs and cavities of the body that open to the outside," such as the vagina and anus. Id. Thus, mucosal HPV types are commonly labeled genital type HPVs because they usually affect the anus and genital areas. Id. Other types of genital HPVs can result in cauliflower-shaped warts on or around the genitals and anus of both men and women. Id. In women, HPV-6 and HPV-11 commonly cause visible warts on the cervix and vagina. Id. "Because these genital warts rarely develop into cancer, HPV-6 and HPV-11 are called "low-risk" viruses." Id. These low-risk types are also known to cause "low-grade cervix cell changes" that do not develop into cancer. Id. Other types of HPV can cause abnormal cells on the lining of the cervix that can turn into cancer years later, such that these types are labeled "high risk." See FDA Press Release, supra note 2. Approximately seventy percent of cervical cancers worldwide are caused by two high-risk strains of HPV, types 16 and 18. Id. Worldwide, over 470,000 new cases of cervical cancer and 233,000 deaths from cervical cancer occur each year. FDA Press Release, supra note 2. According to the Centers for Disease Control and Prevention, in the United States, nearly 9,700 people are diagnosed with cervical cancer each year, and about 3,700 people die from the cancer each year. FDA Press Release, supra note 2.

vaccination, the note will address the strengths and weaknesses of the arguments both for and against a mandatory HPV vaccine. The note will then synthesize the arguments, and recommend that states make mandatory HPV vaccination a long-term goal, instead of rushing to enact HPV mandates when adequate information on the vaccine is unavailable. Finally, the note will conclude that in the meantime, states should focus on educating the public about HPV and cervical cancer and the HPV vaccine, while gathering information on the safety and efficacy of the vaccine and formulating ways to make it practically and financially accessible.

II. HPV and Its Link to Cervical Cancer

Today, over six million people in the United States acquire an HPV infection each year. With over 100 strains of HPV, it infects more people than any other sexually transmitted disease. A person contracts HPV through skin-to-skin—usually genital—contact. Whether HPV symptoms occur depends on the HPV type involved in the infection. While some types may cause genital warts or pre-cancerous changes in the cells of the cervix, vulva, anus, or penis, other types may not cause any noticeable signs of infection.

\[6\] ACS FAQs, supra note 3 (noting "some doctors think [HPV] is as common as the common cold virus").

\[7\] See Gerber, supra note 5, at 495 (providing background for debate among states over mandatory vaccination); See also ACS FAQs, supra note 3 (stating "HPVs are a group of over 100 related viruses").

\[8\] See Public Broadcasting Service (PBS), Facts & Figures: Human Papillomavirus, available at http://www.pbs.org/now/shows/308/hpv-facts.html (last visited Nov. 6, 2007). Transmission typically occurs through direct genital contact during vaginal or anal intercourse. See ACS FAQs, supra note 3. HPV is not spread through bodily fluids, nor does it live in blood or any organs. Id. Genital warts, a common symptom of HPV, are extremely contagious. PBS, supra. Approximately two-thirds of people who have sexual contact with a partner with genital warts will usually develop warts within three months of contact. Id. Even a person that does not have any symptoms of HPV can spread the virus to sexual partners, such that neither sexual partner may realize that the virus is being spread. Id. Although not common, HPV can be transmitted by genital contact without intercourse. See ACS FAQs, supra note 3. The virus has been reported to transmit through oral-genital and hand-genital contact. Id. Also, HPV can be transmitted from mother to newborn during delivery, but such occurrences are rare. Id.


\[10\] See Genital HPV Infection, supra note 3 (noting most people who have a genital HPV infection
HPVs are nonenveloped, double-stranded DNA viruses in the \textit{Papillomaviridae} family.\textsuperscript{11} The virus genome contains separate regions that produce neoplastic proteins E6 and E7, virus production proteins E1, E2, and E5, and virus capsid proteins L1 and L2.\textsuperscript{12} Papillomaviruses initiate infection in the basal layer of the epithelium.\textsuperscript{13} Inside the epithelial cells, the HPV is enclosed in a protective shell made of the L1 viral proteins.\textsuperscript{14} After the virus enters the cell, the viral coat is degraded, and the virus’s genetic material is released into the cell and its nucleus.\textsuperscript{15} Thus, two genes of the virus called E6 and E7 enter the cells, and these genes initiate the production of viral proteins called E6 and E7.\textsuperscript{16}

Viral proteins E6 and E7 then manipulate cell cycle regulators, which produce
“suppressor proteins that do ‘damage surveillance’ in normal cells.”

After infection, differentiating epithelial cells that are normally non-dividing remain in an active cell cycle, and, as a result, a thickened epithelial lesion forms. The virus is released as cells exfoliate from the epithelium, and, with neoplastic progression, the virus could integrate into the host chromosomes, resulting in little virion production.

Over thirty HPV types are transmitted through sexual contact and infect the genital area of men and women. Genital HPV types are categorized on the basis of their epidemiological association with cervical cancer. Low-risk HPVs, such as HPV-6 or HPV-11, usually cause genital warts or low-grade cervix cell changes that rarely develop into cancer. On the other hand, high-risk HPV types have been linked with genital and anal cancers in both men and women.

Actually, HPVs cause approximately 99% of cervical cancers. Of these cancers, the majority are caused by HPV-16 and HPV-18. Yet not all HPV infections lead to serious consequences. Often, a person’s immune system clears an HPV infection with time, such that the person may not even know that he or she was infected. Persistent infection of high-risk types, however, is the single best predictor

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17 NCI Understanding Cancer Series, supra note 14, at Slide 6. These “suppressor proteins” usually cease cell growth when a significant amount of un-repaired genetic damage exists. Id. E6 and E7 also induce chromosomal abnormalities and block apoptosis. Markowitz et al., supra note 9.

18 Markowitz et al., supra note 9.

19 Markowitz et al., supra note 9.

20 Genital HPV Infection, supra note 3. These types of HPV infect the skin of the penis, vulva, or area outside the vagina, or anus, and the linings of the vagina, cervix, or rectum. Id.


22 ACS FAQs, supra note 3. See also supra note 4 (providing overview of warts related to HPVs).

23 ACS FAQs, supra note 3. These types cause low and high-grade cervix cell changes and precancers. Id. “High-risk” types include HPV-16, HPV-18, HPV-31, HPV-35, HPV-39, HPV-45, HPV-51, HPV-52, HPV-58. Id. High-risk HPV types may cause abnormal Pap tests. See Genital HPV Infection, supra note 3. In addition to cervical cancer, HPVs can cause cancer of the vulva, vagina, anus, or penis. Id.

24 ACS FAQs, supra note 3.

25 See ACS FAQs, supra note 3. HPV-16 and HPV-18 cause about 70% of cervical cancers cases. Id.

26 See Genital HPV Infection, supra note 3.

27 See ACS FAQs, supra note 3. Usually HPV goes away on its own and the cervix cells go back to normal. See CDC Q&A, supra note 9. Most people who test positive for genital HPV DNA in research studies often test negative in studies conducted six to twelve months later. ACS FAQs, supra note 3. While this could mean that a person’s immune system completely destroyed
of cervical cancer.\textsuperscript{28}

Through genetic engineering and technology involving the manipulation of genetic material, the HPV vaccine was made out of non-infectious virus-like particles (VLPs), hollow spheres formed by the L1 protein from the virus.\textsuperscript{29} The VLPs trigger an antibody response that is capable of protecting the body against infection by the targeted virus types.\textsuperscript{30} The quadrivalent HPV vaccine is a mixture of four HPV type-specific VLPs prepared from the L1 proteins of HPV 6, 11, 16, and 18 combined with an aluminum adjuvant.\textsuperscript{31} Thus, the vaccine prevents infection with two of the HPV types that can cause cervical cancer— if given before infection with the sexually transmitted virus, the vaccine may protect women from ultimately developing cervical cancer.\textsuperscript{32}

Representative data on the prevalence of HPV among the U.S. population is necessary to establish a baseline against which post-vaccine prevalence can be compared and to ensure cost-effective vaccine distribution.\textsuperscript{33} Researchers have gathered all of the HPV, it could also mean that the infection has just been suppressed to a very low level. \textit{Id.} Even if only a few cells of the cervix remain infected with HPV, the virus could possibly flare up again if the immune system is weakened. \textit{Id.}

\textsuperscript{28} \textit{Genital HPV Infection}, supra note 3. If HPV does not go away, but rather lingers and continues to change cells on a woman’s cervix, these cell changes are known as pre-cancers and can lead to cancer over time if not treated. \textit{See id.}

\textsuperscript{29} NCI, \textit{Statement from the National Cancer Institute on FDA Approval of the HPV Vaccine}, at http://www.cancer.gov/newscenter/pressreleases/HPVStatement (noting importance of technology in developing vaccine) (last visited Nov. 7, 2007) [hereinafter NCI Statement]. The HPV vaccine recently licensed by the U.S. Food and Drug Administration is composed of VLPs that, like the real Human Papillomavirus, have the same outer L1 protein shell, but contain no genetic material inside. \textit{See NCI Understanding Cancer Series, supra note 14, at Slide 7}. This structure enables the vaccine to induce a strong protective immune response. \textit{Id.} When injected into muscle tissue, these particles trigger a strong immune response so the recipient’s body produces antibodies that can recognize and attack the L1 protein on the surface of HPV viruses. \textit{Id.} at slide 8. After the vaccination, the recipient’s immune cells are prepared to fight off future infection by high-risk HPV viruses targeted by the vaccine. \textit{See id.} If an exposure occurs, the vaccinated person’s antibodies against the L1 protein coat the virus and prevent it from releasing its genetic material. \textit{See id.}

\textsuperscript{30} \textit{See NCI Statement, supra note 29.}

\textsuperscript{31} \textit{See Markowitz et al., supra note 9.} The VLPs “trigger an antibody response that is capable of protecting the body against infection by the targeted virus types.” \textit{See NCI Statement, supra note 29.}

\textsuperscript{32} \textit{See Markowitz et al., supra note 9.}

\textsuperscript{33} \textit{See HPI’ Prevalence, supra note 21} (detailing HPV study results); \textit{see also} Susan C. Weller & Lawrence R. Stanberry, \textit{Estimating the Population Prevalence of HPV}, 297(8) J. AM. MED. ASS’N 876, 878, Feb. 28, 2007 (examining the national prevalence data). Prevalence is the proportion of both new and old cases of HPV present at a single point in time. \textit{Id.} at 877. Estimates of HPV
information on the prevalence and incidence of the virus largely from clinic-based populations, including family planning and sexually transmitted disease or university health clinic patients. Thus, while researchers have conducted numerous studies of HPV infection in the U.S., these studies have mainly been conducted in select societal subgroups, so the results may improperly represent the U.S. population as a whole. Two studies have reported prevalence in U.S. representative, population-based samples.

In 2001-2002, as part of the National Longitudinal Study of Adolescent Health ("ADHEALTH"), sexually-active women aged eighteen to twenty-five years were tested for HPV. Also, in February 2007, the National Health and Nutritional Examination Survey ("NHANES") published the first estimate of overall prevalence of HPV among U.S. women across a broad age range and representative of the U.S. population. Although the NHANES study showed a higher prevalence of HPV in participants than that of the ADHEALTH study, the data is difficult to compare due to the different ages of the participants, the biological samples collected, the methods for detecting HPV, and the HPV types reported.

The objective of the NHANES study was to reduce the number of new HPV cases to help lower the overall number of cases of high risk subtypes related to cervical cancer in females. NHANES used a "representative sample of the U.S. non-prevalence based on specific clinic populations are inappropriate representations of the entire U.S. population because prevalence can vary by type of population studied. Id. at 876.

See Markowitz et al., supra note 9.

Lisa E. Manhart, et al., Human Papillomavirus Infection Among Sexually Active Young Women in the United States: Implications for Developing a Vaccination Strategy, 8 SEX. TRANS. DIS. 502, 502-508 (2006). In studies of college women, between twenty and forty six percent of participants have tested positive for infection. Id. In clinic-based population studies, as much as sixty-four percent of participants have tested positive. Id. College and clinic populations, however, represent a select segment of society. Id. Although some risk factors for sexually transmitted infection (STI) identified in clinic-based and college-based studies are also common to the general population samples, certain risk factors may also be overcompensated or undercompensated. Id.

See Markowitz et al., supra note 9. See also Manhart, supra note 35; HPV Prevalence, supra note 21, at 813-819.

See Manhart, supra note 35, at 503.

See HPV Prevalence, supra note 21, at 814 (providing overview of clinical study method and results); see also NCI Study, supra note 4 (discussing results from study of women in the U.S. regarding HPV virus). Study participants were all aged nineteen to fifty-nine. See HPV Prevalence, supra note 21, at 814.

See Susan C. Weller & Lawrence R. Stanberry, supra note 33, at 877.

See NHANES 2003-2004 Data Documentation, Laboratory Assessment: Lab 37 Human
institutionalized civilian population.” Each participant provided a self-collected vaginal swab specimen that was analyzed for HPV DNA by L1 consensus polymerase chain reaction followed by type-specific hybridization. Participants also provided demographic and sexual behavioral information.

The results of the NHANES study showed that HPV infected nearly 27% percent of the participants, and prevalence was highest in women between the ages of twenty and twenty-four. Overall, prevalence of high and low-risk HPV types was


41 Id. (describing the study population and study design). NHANES obtained its sample “by using a complex, stratified, multistage probability sample design with unequal probabilities of selection to obtain a nationally representative sample.” HPV Prevalence, supra note 21, at 814. Thus, certain subgroups were over-sampled. Id. Of the 2,482 females ages fourteen to fifty-nine years who were interviewed at home for the 2003-2004 study, 2,387 were examined. Id. at 814. The majority of participants were examined in a mobile examination center. Id. at 814.

42 See HPV Prevalence, supra note 21, at 814. A total of 2,026 participants submitted cervicovaginal samples. Id. Each female was given a collection device, a small foam swab on a plastic handle packaged in an individual recloseable plastic sleeve. Id. Participants were instructed on how to insert the swab properly into the vagina, and privately collected the samples in a bathroom. Id. Afterwards, NHANES personnel stored the swabs at room temperature and mailed them to the Centers for Disease Control and Prevention laboratory for processing. Id. Within one month of sample collection, DNA was extracted using slight modifications of the QIAmp Mini Kit protocol. Id. at 814. Swabs were incubated at 56°C for at least twelve hours in proteinase K lysis solution. Id. HPV detection and typing was performed by using the Roche prototype line blot assay. Id. This assay uses HPV L1 consensus polymerase chain reaction with biotinylated PGMY09/11 primer sets and β-globin as an internal control for sample amplification. See HPV Prevalence, supra note 21, at 814.

43 See HPV Prevalence, supra note 21 at 813. Race and ethnicity were self-reported into categories. Id. Poverty index was calculated by dividing total family income by the poverty threshold index, adjusted for family size at year of interview. Id. Sex was defined as vaginal, oral or anal sex, and those participants that reported at least one lifetime partner were asked additional questions such as age of first sexual encounter and number and gender of sex partners in last twelve months. Id. 44 See HPV Prevalence, supra note 21, at 815 (26.8% vaginal swab specimens tested positive for HPV DNA). According to 2000 Census data, this corresponded to 24.9 million females aged fourteen to fifty-nine with prevalent HPV infection. Id. HPV incidence was about 45% among females aged twenty to twenty-four years. Id. at 816. For those aged fourteen to nineteen, HPV incidence was 24.5%. See HPV Prevalence, supra note 21, at 816. For those aged twenty-five to twenty-nine years, HPV prevalence was 27.4%. Id. For those aged thirty to thirty-nine, HPV incidence was 27.5%. See HPV Prevalence, supra note 21, at 815. For those aged forty to forty-nine years, HPV prevalence was 25.2%. Id. Finally, the results showed that HPV prevalence among participants aged fifty to fifty-nine was 19.6%. Id.
15.2% and 17.8%, respectively. HPV types 6, 11, 16, and 18 were detected in 3.4% of all participants. The study showed that "the burden of prevalent HPV infection among women was higher than previous estimates." Before the NHANES study in 2003-2004, no national surveillance system existed to measure the full burden of HPV infection and no reliable information on the prevalence of HPV among the national population was available. The ADHEALTH study assessed the prevalence of HPV types 6, 11, 16, and 18 among a group of 3,262 sexually active women aged eighteen to twenty-five. Participants completed a computer-assisted survey interview and provided a urine specimen.

In the ADHEALTH study, overall HPV prevalence was 26.9% among the participants. Among participants aged eighteen to twenty-one, HPV prevalence was approximately 30% and it then declined with age. High-risk HPV types were found in 20.4% of the women tested, and low-risk HPV types were found in 4.8% of the participants.

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45 See HPV Prevalence, supra note 21, at 816.
46 HPV Prevalence, supra note 21, at 819. HPV-6 was detected in 1.3% of swab specimens. See HPV Prevalence, supra note 21, at 816. HPV-11 was detected in 0.1%. Id. HPV-16 was detected in 1.5%. Id. HPV-18 was detected in 0.8%. Id.
47 See HPV Prevalence, supra note 21, at 819 (see results of ADHEALTH study discussed later).
48 See NHANES Data, supra note 40 (summarizing method of detecting HPV DNA in vaginal swabs). As of the date of the ADHEALTH HPV prevalence study, the sole investigations of HPV in the general population estimated the prevalence of serum antibodies to a single type, HPV-16. See Manhart, supra note 37, at 502-503. See also Eileen F. Dunne, et al., Seroprevalence of human papillomavirus Type 16 in Children, 191 J. Infect. Dis. 1817 (2005) [hereinafter Seroprevalence Study]. The study examined the seroprevalance of HPV-16 in a representative sample of U.S. children aged six to eleven years. Id.
49 See Manhart, supra note 35, at 502. The women selected for the HPV sub-sample had a mean age of 21.7 years and were 68% percent Caucasian. Id. at 503.
50 Manhart, supra note 35, at 502. The computer survey collected extensive data on demographic, social, and behavioral characteristics. Id. at 503. Although urine specimens are less sensitive for HPV detection than cervical swab specimens, they are deemed appropriate for population-based epidemiological studies where cervical swabs that necessitate a clinical examination cannot be obtained. Id. The urine specimens were thawed, aliquoted, and spun, and the resulting cell pellet was re-suspended in 600 μL STM (storage and transfer media from Digene Corporation) and digested with 20 μg/ml protease K. DNA was isolated using QIAamp blood DNA minicolumn. Id.
51 See Manhart, supra note 35, at 504.
52 See Manhart, supra note 35, at 504.
53 See Manhart, supra note 35, at 504. HPV-16 was the most prevalent identified type. Id. HPV types 6 or 11 were detected in 2.2% of all women, while types 16 or 18 were present in 7.8% of women. Id. "Type 16 or 18 comprised 38% of all infections with a high-risk type." Id. at 504.
The ADHEALTH study produced the first data on HPV prevalence among a target population group in the United States. The study also provided information on the common characteristics associated with HPV infection. While some demographic characteristics were predictive of HPV infection, other socioeconomic factors were not. Overall, the ADHEALTH study demonstrated that HPV infection was relatively high in young women with low-risk sexual behaviors and that no clear set of factors defined a high-risk group.

Both the ADHEALTH and NHANES studies suggest that HPV is age-dependent with the highest prevalence among younger women. Additionally, the data from the two studies reveals that the prevalence of any type of HPV infection is 49.3% among females aged twenty to twenty-four in the NHANES sample, compared with 26.9% among the females aged eighteen to twenty-five years in the ADHEALTH study. This difference in prevalence estimates may, in part, be explained by the different methods for detecting HPV. It is unlikely, however, that the difference in

54 See Manhart, supra note 35, at 507. Although the large sample size and sampling scheme of the ADHEALTH study results were representative estimates of HPV prevalence in the U.S., the results should not be extrapolated outside the age range of the study participants. Id.

55 Manhart, supra note 35, at 504.

56 See Manhart, supra note 35, at 505. Race, ethnicity, and marital status were predictive for HPV infection. Id. at 504-505. HPV prevalence was highest among African and Native Americans, at 35% and 37.1%, respectively, and lowest among Asians at 17.7%. See id. at 505. Further, HPV prevalence was positively associated with women participants who were single and had never been married and with women who had reported three or more lifetime sex partners. Id. at 506 (data table). Even among women who reported only one vaginal sex partner in their lifetime, 14% tested positive for a genital HPV infection. See Manhart, supra note 35, at 505. Further risk factors were also associated with HPV prevalence. Id. at 506. The NHANES study also provided information on the factors associated with HPV DNA detection, including age, race, marital status, education, poverty index, and country of birth. See HPV Prevalence, supra note 21, at 816-817.

57 See Manhart, supra note 35, at 507.

58 See HPV Prevalence, supra note 22, at 817. In the ADHEALTH study, 2.2% of the participants aged eighteen to twenty-five tested positively for HPV types 6 or 11. Id. at 817. The prevalence of HPV-16 or HPV-18 was 7.8%. Id. In the NHANES study, among the women participants aged twenty to twenty-five, the prevalence of HPV-6 or HPV-11 was similar to that found by the ADHEALTH study. Id. The prevalence of HPV-16 or HPV-18, however, was lower. Id.

59 See Susan C. Weller & Lawrence R. Stanberry, supra note 33, at 877. Thus, for a similar subpopulation of sexually active young women, the prevalence of all types of HPV infection is approximately two times higher in the NHANES study than in the ADHEALTH study. Id. There were no prior evaluations in the U.S. population using self-collected vaginal swabs to which the data from the NHANES study could be compared. See HPV Prevalence, supra note 21, at 818.

60 See Susan C. Weller & Lawrence R. Stanberry, supra note 33, at 877. Urine-based assessments
specimen types used in the two studies entirely accounts for the significant variance in the prevalence estimates.61

There is no cure for HPV; however, HPV treatment is directed at HPV-associated lesions.62 For treatment of genital warts and cervical, vaginal and vulvar cancer precursors, physicians use local approaches that remove the lesion.63 Women can prevent cervical cancer through regular cancer screening, Papinicolau testing ("Pap testing").64 The U.S. Preventive Services Task Force recommends that all women should have a Pap test for cervical cancer within three years of beginning sexual activity, or by the age of twenty-one years, which ever occurs first, and then every three years thereafter.65

Follow-up exams after abnormal Pap test findings are critical for determining necessary preventative measures.66 Often, these screening programs involve multiple visits and follow-up treatment which can be costly.67 The necessity for Pap testing is demonstrated by the fact that between 60% and 80% of U.S. women with newly diagnosed invasive cervical cancer have not had a Pap smear in the past five years, and

for HPV are somewhat less sensitive than assessments for HPV performed on cervical swab specimens, and true prevalence in the NHANES study may be closer to 33% than 26.9%. See Manhart, supra note 35, at 507.
61 See Susan C. Weller & Lawrence R. Stanberry, supra note 33, at 877. Compared to using cervicovaginal swabs, using vaginal swabs to detect the prevalence of HPV DNA may result in an underestimated prevalence by a factor of 1.2 to 1.3. Id. "Given that urine specimens may underestimate the prevalence of HPV, it is surprising that the prevalences of some high-risk types are lower in the NHANES sample than in ADHEALTH, where the estimates are based on urine samples." Id. In the ADHEALTH study, 7.8% of the sexually active participants aged eighteen to twenty-five years had either HPV-16 or HPV-18. Id. In the NHANES study, however, only 3.5% of sexually active eighteen to twenty-five year-olds had HPV-16 or HPV-18. Id.; see also HPV Prevalence, supra note 21, at 817.

62 See Markowitz et al., supra note 9.
63 Markowitz et al., supra note 9. Available therapies of HPV-related lesions might reduce, but most likely do not eliminate, infectiousness. Id.
64 See Eileen F. Dunne & Lauri E. Markowitz, supra note 12, at 626.
65 See Markowitz et al., supra note 9.
67 See Eileen F. Dunne & Lauri E. Markowitz, supra note 12, at 626. Primarily because of the cost of screening, follow-up, and treatment that is associated with abnormal Pap test findings, HPV is one of the most expensive STIs. Id.
many of these women have never had a Pap test.\footnote{68}\\n
III. The Development and Introduction of the HPV Vaccine\\n
Currently, the FDA has approved only one HPV vaccine: Gardasil, a product by Merck.\footnote{69} Based on The Advisory Committee on Immunization Practices ("ACIP") recommendations, the vaccine is available to females between the ages of nine and twenty-six.\footnote{70} The vaccine is given in three doses over the course of six months.\footnote{71} Because the vaccine will not prevent diseases related to HPV types previously acquired, females should ideally get vaccinated before their first sexual contact that could expose them to HPV.\footnote{72} While even those women who have already acquired one or more types of HPV may benefit from the vaccination if they have not acquired one of the four types of HPV targeted by the vaccine, the vaccine does not treat existing HPV infection,

\footnote{68 See ACS Prevention and Detection, supra note 66. Although Pap testing rates for all age and ethnic groups have increased over recent years, certain groups continue to have low screening rates. See Markowitz et al., supra note 9. These groups include women with less than a high school education, foreign-born women, women without health insurance, and certain racial/ethnic populations, such as Hispanics and Asians. Id.\\n
69 See HPV Vaccine, supra note 5. GlaxoSmithKline has also developed a vaccine called Cervarix to target HPV-16 and HPV-18, but is awaiting FDA approval. Id.\\n
70 See Markowitz et al., supra note 9. The ACIP HPV workgroup began meeting in February 2004 to begin reviewing data related to the quadrivalent HPV vaccine. Id. The workgroup teleconferenced and met three times a year to review published and unpublished data from the HPV vaccine clinical trials, such as data on the safety, immunogenicity, and efficacy. Id. The workgroup also reviewed data on the epidemiology and natural history of HPV, vaccine acceptability, and sexual behavior in the U.S. Id. Additionally, they looked to expert opinion when necessary. Id. The workgroup presented its final recommendations to ACIP at a June 2006 ACIP meeting. Id. After making a few minor modifications, the ACIP approved the recommendations at the June 2006 meeting. Id. The ACIP further modified the ACIP statement during the subsequent review process at the CDC and will continue to review and update recommendations as more data about the HPV vaccine from clinical trials becomes available in the future. Id. Although the vaccine is only available to females between the ages of nine and twenty-six, researchers have begun testing the effect of the vaccination on older women. See CDC Q&As, supra note 9. If research shows that the vaccine is safe and effective for older women, the FDA may approve HPV vaccination for a broader age group of females. Id.\\n
71 See CDC Q&As, supra note 9; see also Markowitz et al., supra note 9. The second and third shots should be administered two and six months, respectively, after the first shot. See Markowitz et al., supra note 9.\\n
72 See CDC Q&As, supra note 9 (noting importance of vaccination before infection). A CDC study shows that 13% of American girls are sexually active by the age of fifteen, 43% are sexually active by the age of seventeen, and 70% are sexually active by the age of nineteen. See Cynthia Dallard, Legislating Against Arousal: The Growing Divide Between Federal Policy and Teenage Sexual Behavior, 9(3) GUTTMACHER POL’Y REV. 12, 14 (2006).}
genital warts, pre-cancers or cancers.\textsuperscript{73}

Clinical studies in the U.S. and worldwide have shown Gardasil to be nearly 100% effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts, all caused by infection with the HPV types targeted by the vaccine.\textsuperscript{74} Further, the safety of the HPV vaccine has been tested in over 11,000 females worldwide, with the most adverse effect of the vaccine being mild or moderate local reactions, such as soreness at the injection site.\textsuperscript{75} Studies have also shown that the

\textsuperscript{73} See CDC Q\&As, supra note 9; see also CDC, HPV Vaccine Questions \& Answers, available at http://www.cdc.gov/std/ hpv/hpv-vaccine.pdf, 2 (last visited Nov. 25, 2007) [hereinafter HPV Q\&As]. Girls and women do not need to be screened for HPV, either through an HPV test or Pap test, before vaccination. See HPV Q\&As, supra. In clinical studies of the efficacy of the HPV vaccine (mentioned in next footnote), participants were enrolled even if they were HPV DNA or antibody positive, such that researchers were able to evaluate the efficacy of the vaccine in females infected with a vaccine HPV type at the time of the vaccination. See Markowitz et al., supra note 9. The study took into account that 27% of participants indicated prior exposure or infection with a vaccine HPV type. Id. Based on data from four clinical studies:

[A]mong persons seropositive to the relevant HPV type but HPV DNA negative, efficacy against CIN 2/3 or AIS caused by that type was 100%. Among women who were HPV DNA positive but seronegative, efficacy was 31.2%. Among women who were both seropositive and HPV DNA positive, efficacy against CIN 2/3 caused by that type was -25.8%. Id.

\textsuperscript{74} See FDA Press Release, supra note 2. In one U.S. study and three multinational studies, 21,000 women were given either the vaccine or a placebo to test the effectiveness of the HPV vaccine in women aged sixteen to twenty-six. Id. The studies used pre-specified endpoints to evaluate the impact of the vaccine in preventing HPV-related infection and disease. See Markowitz et al., supra note 9. Analysis of participants through sixty months after the third dose resulted in an efficacy against vaccine HPV type persistent infection or disease of 95.8% and an efficacy against vaccine-type-related CIN or external genital lesions at 100 percent. Id. While cervical cancer is unlikely to develop in only five years, the demonstrated prevention of cervical precancerous lesions, precancerous vaginal and vulvar lesions, and genital warts caused by HPV types against which the vaccine is targeted suggest a high probability that the vaccine will also prevent cervical cancer. See FDA Press Release, supra note 2.

\textsuperscript{75} See FDA Press Release, supra note 2. Of the total reports to the Vaccine Adverse Event Reporting System (VAERS), nearly 95% of reports have been classified as non-serious. See CDC, HPV: Gardasil and GBS, available at http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/hpv-gardasil-gbs.pdf (last visited Nov. 7, 2007) [hereinafter Gardasil and GBS]. “VAERS is a national program that monitors the safety of vaccines after they are licensed” and accepts reports submitted by anyone. Id. The serious adverse effects reported as a result of a Gardasil vaccination include thirteen unconfirmed reports of Guillain-Barre Syndrome (GBS). See CDC Q\&As, supra note 9. Some of the alleged reports of GBS did not occur within six weeks after Gardasil vaccination and may have been associated with another vaccine received simultaneously with the Gardasil vaccine, or may have occurred by coincidence following vaccination but not because of vaccination. Id.; see also Gardasil and GBS, supra. Four deaths of
vaccine is safe and immunogenic for girls between the ages of nine and fifteen; however, researchers have not yet evaluated the effectiveness of the vaccine for this age group.\textsuperscript{76} The FDA's approval of Gardasil is conditioned upon Merck's assurance that it will continue to study the safety and efficacy of the vaccine.\textsuperscript{77}

The retail price for the Gardasil vaccine is $120 per dose, or $360 for the full series.\textsuperscript{78} Most large private insurance companies usually cover the costs of ACIP-recommended vaccines.\textsuperscript{79} Often, however, there is a short lag-time between when the vaccine is recommended and when it is both available and covered by insurance plans.\textsuperscript{80}

The CDC has added Gardasil to its Vaccine for Children Program ("VFC"), which covers the cost of the vaccination for children under nineteen years old insured by Medicaid, Alaska Native and American Indian children, and some uninsured and underinsured children.\textsuperscript{81} For those women older than nineteen who receive Medicaid, vaccines are considered an optional benefit, and each state decides whether it will cover the service.\textsuperscript{82} Additionally, some states provide free or low-cost vaccines at public

women who received the HPV vaccine have also been reported, but they do not appear to have been caused by the vaccination. See CDC Q\&As, supra note 9.\textsuperscript{76} See Lawrence O. Gostin & Catherine D. DeAngelis, Mandatory HPV Vaccination: Public Health vs. Private Wealth, 297(17) J. AM. MED. ASS'N 1921, 1921 (2007). The immune response of the female participants aged nine to fifteen was as good as the response found in females aged sixteen to twenty-six, indicating that the vaccine should have a similar effect on both age groups.\textsuperscript{77} Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1921. Merck has planned follow-up studies to determine the duration of protection among women enrolled in the phase III studies through three years after the third vaccine dose. See Markowitz et al., supra note 9. Follow-ups on approximately 5,500 women enrolled in one of the phase III studies in the Nordic countries will also provide data on the duration of the quadrivalent HPV vaccine protection. Id. These women will be followed for at least fourteen years, including serologic testing conducted five and ten years after vaccination. Id.

The Gardasil vaccine costs far more than any other commonly used vaccine. See Jane E. Brody, Personal Health; HPV Vaccine: Few Risks, Many Benefits, N.Y. TIMES, May 15, 2007, available at http://www.nytimes.com/2007/05/15/health/15brod.html. Further, if a booster shot is needed later to ensure continuous effectiveness of the HPV vaccine, the potential fourth dose could cost another $120. Id.


See HPV Vaccine Q\&As, supra note 73.\textsuperscript{80} See Markowitz et al., supra note 9. Over 45,000 sites provide VFC vaccines, including hospitals and private and public clinics. See HPV Vaccine Q\&As, supra note 73. Under the VFC Program, children and teens can also get vaccines through Federally Qualified Health Centers or Rural Health Centers. Id; See also Kaiser Background Brief, supra note 79.

See Kaiser Background Brief, supra note 79.
health programs for those without health insurance to cover the vaccine cost. Finally, Merck has announced that it will set up a program through which it will provide free vaccines, including Gardasil, to women aged nineteen years and older who visit private practices that provide Merck vaccines.

IV. State Legislation in Response to the HPV Vaccine

After ACIP makes its recommendations, each state decides whether to make the vaccine mandatory for childcare and school entrance. No federal laws mandate vaccination, and the mandatory vaccination laws vary from state to state. Within a year of the FDA approval, the majority of states and the District of Columbia (D.C.) had proposed legislation to require, fund, or educate the public about the HPV vaccine. Several states have enacted this legislation. In addition, many states and

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83 See Kaiser Background Brief, supra note 79.
84 See Kaiser Background Brief, supra note 79.
85 See Kaiser Background Brief, supra note 79.
86 See Kaiser Background Brief, supra note 79.
87 See Gerber, supra note 5. The Arizona legislature proposed a bill to allocate $2.9 billion from the state general fund in the fiscal year 2007-2008 to cover the cost of HPV vaccinations of women between the ages of twenty-one and twenty-six. See S.B. 1385, Reg. Sess. (Az. 2007); see also HPV Vaccine, supra note 5. Further, the bill provides federal matching of $5.6 million. Id. Another Arizona proposed bill appropriates $200,000 for outreach and education programs on immunizations recommended by the ACIP, including the HPV vaccine. See S.B. 1437 (Az. 2007). An additional bill proposed by the Arizona legislature would require insurance coverage of the HPV vaccine. See S.B. 1502 (Az. 2007). In Arkansas, Senator Sue Madison introduced a bill to require the Department of Health and Human Services to institute a program to provide HPV vaccinations to all girls twelve years or older, but the senator withdrew the bill in March 2007. See S.B. 954, Reg. Sess. (Ar. 2007); see also HPV Vaccine, supra note 5. In California, the state legislature proposed a bill to expand cervical cancer screening under existing insurance plans to include HPV vaccinations with a referral from a healthcare provider, but the governor vetoed the bill on October 14, 2007. Id.; see also A.B. 1429 (Cal. 2007). In Colorado, the legislature is considering a bill that would request a Medicaid waiver from the federal government to provide the HPV vaccine for girls aged twelve to eighteen with parental consent. See HPV Vaccine, supra note 5. Proposed legislation in Connecticut, if enacted, would require the Department of Health to develop standards for early immunization against HPV, provide coverage for the vaccine through the state’s insurance plan, and create an awareness campaign on prevention strategies and treatment for cervical cancer and HPV. See S.B. 86, H.B. 5485 & 6085 (Ct. 2007); see also HPV Vaccine, supra note 5. In Florida, a proposed Senate bill would have allowed the Board of Medicine and the Board of Osteopathic Medicine to establish guidelines concerning information given to parents and guardians on HPV and also would have required insurance policies to cover the HPV vaccine; however, the Senator who sponsored the bill withdrew it. See S.B. 86, Reg. Sess. (2007 Fl.); see also HPV Vaccine, supra note 5. Other states considering legislation relating to coverage and awareness of HPV and the HPV vaccine include Georgia, Hawaii, Illinois, Indiana,
D.C. have introduced legislation to specifically require the HPV vaccine for school entrance. Michigan was the first state to introduce legislation to require the HPV vaccine. Iowa, Kansas, Kentucky, Michigan, Missouri, Mississippi, Nebraska, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Vermont, Virginia, and West Virginia. Id.

88 See HPV Vaccine, supra note 5. States that have enacted legislation relating to HPV include Colorado, Indiana, Iowa, Maine, Maryland, Minnesota, Nevada, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Dakota, Texas, Utah, Virginia and Washington. Id. Further, the Colorado legislature has enacted laws that provide state funding for HPV vaccination. Id. Colorado allocates 4% of state tobacco litigation settlement money to the cervical cancer immunization fund and creates a cervical cancer immunization program that encourages the use of the HPV vaccine and places the vaccine on the list of Medicaid benefits. Id. The Colorado House Bill also requires that certain health insurance providers cover the full cost of a cervical cancer vaccination for those females for whom the ACIP recommends a vaccination. Id; see also H.B. 1301 (Co. 2007). An Illinois law requires insurance companies to provide coverage for the vaccine and the Department of Health to cover vaccination of girls who are uninsured. See HPV Vaccine, supra note 5; S.B. 937 (Ill. 2007). In Maryland, two bills relating to the HPV vaccine have been signed into law. See HPV Vaccine, supra note 5. A House bill creates a Task Force to recommend a plan to implement a HPV vaccine program in the state and to suggest the requirements, costs, and education efforts for the vaccine. Id.; see also H.B. 1049 (Md. 2007). A Maryland Senate bill that was signed into law establishes the HPV subcommittee in the Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan. See HPV Vaccine, supra note 5; S.B. 774 (Md. 2007). A Minnesota law mandates that the Commissioner of Health reconvene the cervical cancer elimination study so that it may conduct a study on HPV vaccine, its risks, benefits, costs, efficacy, and also study the availability of the HPV vaccine with the assistance of the Minnesota Immunization Practices Advisory Committee. See HPV Vaccine, supra note 5; H.F. 1078 (Mn. 2007). Nevada has enacted a law that requires insurance companies to cover the cost of the HPV vaccination of policyholders and their dependents without prior authorization. See S.B. 409 (Nv. 2007); see also HPV Vaccine, supra note 5. The New Mexico legislature passed a law that requires insurance plans in the state to cover the FDA-approved HPV vaccine for girls aged nine to fourteen, and provides that existing deductibles and coinsurance may apply. See HPV Vaccine, supra note 5; S.B. 407 (N.M. 2007). Further, a North Carolina law requires the Department of Health to distribute information on HPV and the vaccine through schools to all parents of children in grades five through twelve. See HPV Vaccine, supra note 5; S.B. 260; H.B. 938. In Rhode Island, a House Bill was signed into law to require insurance coverage for the cervical cancer vaccine. See HPV Vaccine, supra note 5, H.B. 5061 (R.I. 2007). In South Dakota, the state legislature approved a bill that authorizes $9.2 million in funding to provide HPV vaccines at no cost to girls and women between the ages of eleven and eighteen. See HPV Vaccine, supra note 5; H.B. 1061 (S.D. 2007). The program is voluntary. Id. Furthermore, Utah enacted a law that authorizes the Department of Health to create an awareness campaign on the causes, prevention, and risks of cervical cancer. See H.B. 1061 (S.D. 2007); HPV Vaccine, supra note 5.

89 See Gerber, supra note 5. Proposed legislation in Connecticut includes a school vaccine mandate for girls before entering the sixth grade. See HPV Vaccine, supra note 5; H.B. 6977, 2007 Reg. Sess. (Conn. 2007). Further, a Colorado Senate bill proposes that, prior to admission to any state school, all girls between the ages of eleven and twelve and their parents and guardians be
vaccine for girls entering the sixth grade as of September 2006, just three months after the FDA’s approval of the vaccine.\textsuperscript{90} Also, at the beginning of February 2007, Texas

given information about the HPV vaccine and the link between HPV and cervical cancer. \textit{Id.; see also} S.B. 80, 66th Gen. Assem., 1st Reg. Sess. (Colo. 2007). No girl over the age of twelve can enter school without showing documentation that she received the HPV vaccine or that, after receiving information about HPV and the HPV vaccine, her parent or guardian opted not to vaccinate the child. \textit{Id.} The proposed Colorado legislation mandates that the Executive Director of the Department of Public Health and Environment decide the content of the information given to parents. \textit{Id.} In addition, proposed legislation in D.C., if enacted, would require female students to show proof of vaccination before enrolling in the sixth grade in public schools, unless their parent or legal guardian chooses to opt out of the requirement. \textit{See HPV Vaccine, supra note 5; B17-0030, 2007 Leg. (D.C. 2007). Parents and guardians would be able to opt out of the requirement for any reason. Id. A proposed Senate bill in Florida would require girls aged eleven and twelve years old in the state to be vaccinated against HPV before beginning the 2008-2009 school year or show proof that after their parent or guardian was informed of the vaccine they opted out for their child. \textit{See HPV Vaccine, supra note 5; S.B. 660, 2007 Leg., Reg. Sess. (Fl. 2007); See also} The Henry J. Kaiser Family Foundation, \textit{State Politics & Policy: Actions Taken on HPV Vaccine Proposals in Arkansas, Connecticut, Florida, Georgia, South Dakota, Texas, Virginia, Feb. 22, 2007, available at http://www.kaisernetwork.org/daily-reports/rep_index.cfm?hint=2&DR_ID=43090. In February 2007, however, the Senator who sponsored the bill announced that he would delay enforcement of the requirement until the 2009-2110 school year because of the lack of information regarding the vaccine's long-term safety and parents' concerns about discussing HPV with their daughters before they are ready. \textit{Id.} The Florida Senate bill died in the Committee on Education Pre-K Appropriations. \textit{See HPV Vaccine, supra note 5. A similar Florida House Bill for mandatory vaccination to begin in the 2008-2009 school year was under consideration, but died in the Policy & Budget Council, as of May 2007. \textit{See HPV Vaccine, supra note 5; H.B. 561, 2007 Leg., Reg. Sess. (Fl. 2007). A Georgia Senate bill, if passed, would require female students to be vaccinated for HPV prior to admission to the sixth grade at any state school. \textit{See HPV Vaccine, supra note 5; S.B. 155, 2007 Leg., Reg. Sess. (Ga. 2007). In addition to an exemption for religious views, the measure allows an exemption for parents and guardians who cannot afford the vaccine. \textit{See Kaiser Family Foundation, supra. Proposed Illinois legislation also requires HPV vaccination of girls entering the sixth grade with exemptions, in addition to requiring the school to track the number of immunized children attending the school. \textit{See HPV Vaccine, supra note 5; H.B. 115, 95th Gen. Assem. (Ill. 2007). The Kentucky legislature is considering a bill that would require HPV vaccination for all girls entering middle school. \textit{See HPV Vaccine, supra note 5; H.B. 345, 2007 Leg., Reg. Sess. (Ky. 2007). In addition, legislatures of Massachusetts, Michigan, Missouri, Minnesota, Mississippi, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Carolina, Vermont, and West Virginia are currently reviewing proposals to make HPV vaccination a requirement for school entry. \textit{See HPV Vaccine, supra note 5. \textit{See HPV Vaccine, supra note 5; see also} Gerber, supra note 5. The Michigan Senate sought to increase HPV vaccination and awareness of the vaccine by requiring parents and guardians of girls entering the sixth grade to submit either a statement from a physician that the child had received the HPV vaccine or a statement indicating that the parent or guardian had elected to not vaccinate his or her child after receiving information about the connection between HPV and cervical cancer. \textit{See The Henry J. Kaiser Family Foundation, HPV Vaccine Legislation Introduced in
enacted a bill by executive order, making Texas the first state to enact a vaccination mandate (although it was later overruled), which provided that, as of September 2008, all females entering the sixth grade were to receive the vaccination, with certain exceptions.91 Several other states’ legislative proposals for mandatory school vaccine have also met with resistance and have been withdrawn or referred to a state committee for further review.92 Currently, Virginia is the only state with a mandatory HPV vaccine requirement for all females entering the sixth grade.93

A driving force behind the introduction of state legislation mandating the HPV vaccine for young girls was funding provided by the vaccine manufacturer itself, Merck.94 Merck channeled money for its state mandatory legislation campaign through

Colorado, Connecticut, Kansas, Michigan, Wisconsin; Maryland Bill to Be Withdrawn, Feb. 1, 2007, available at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=42648. Currently, the Michigan legislation for mandatory school HPV vaccination has not been enacted, but rather has been referred to the Committee on Health Policy. See HPV ‘ I ‘accine, supra note 5; see also S.B. 132, 94th Leg., Reg. Sess. (Mich. 2007).

93 See Gerber, supra note 5; see also HPV ‘ I ‘accine, supra note 5. In California, legislators introduced a bill to require all girls entering the sixth grade to receive the HPV vaccine, but the bill was withdrawn for further consideration. See HPV ‘ I ‘accine, supra note 5, A.B. 16, 2007-8 Leg., Reg Sess. (Ca. 2007). A Maryland Senate Bill to require cervical cancer vaccination for all girls entering sixth grade at state schools was also withdrawn. See HPV ‘ I ‘accine, supra note 5; S.B. 54, 2007 Leg., Reg. Sess. (Md. 2007).

a third party, Women in Government. In February 2007, the drug conglomerate announced that it was canceling its nationwide lobbying efforts to make its HPV vaccine mandatory for young girls to attend public school. Because of the controversy surrounding the HPV vaccine requirement among parents, advocacy groups, and public health experts, Merck officials feared that its lobbying campaign could hinder adoption of the vaccine overall.

V. The Debate Over a Mandatory Vaccine

Although the HPV vaccine presents great potential to reduce the incidence of HPV and cervical cancer, the general public, health officials, and policymakers are apprehensive of the rush of responsive legislation to make HPV vaccination mandatory for school admission. Some opponents of the legislation maintain that mandatory vaccination preempts parental authority to make health decisions for one’s child, while others have raised concerns about the cost and safety of the vaccine. Still others have moral objections to mandating a vaccine for a sexually transmitted disease. Overall, though, adolescent and adult women are optimistic about the availability of information on HPV infection, transmission, detection, and prevention, and they have widely accepted idea of the HPV vaccine.

96 See Associated Press, supra note 94.
97 See Andrew Pollack & Stephanie Saul, Merck to Halt Lobbying for Vaccine for Girls, N.Y. TIMES, Feb. 21, 2007, available at http://www.nytimes.com/2007/02/21/business/21merck.html?ex=1329714000&en=1e44a0345d69131&ei=5090&partner=rssuserland&emc=rss. “Public health authorities, pediatricians, and infectious disease specialists, rather than political bodies, should drive mandatory vaccination decisions and policies.” See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922. Since Merck stands to profit from mandatory HPV vaccinations, it is inappropriate for the company to finance efforts to propose state legislation for the vaccine requirement. Id. “Private wealth should never trump public health.” Id.
98 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922; see also Gerber, supra note 5.
99 See Grady, supra note 1; HPV Vaccine, supra note 5; see also Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922.
100 HPV Vaccine, supra note 5. Although physicians can present the HPV vaccine to parents and adolescents as a vaccine for cervical cancer, any vaccine that targets the HPV types responsible for both genital warts and cervical cancer would most likely be categorized as an STI vaccine. See Gregory D. Zimet, Improving Adolescent Health: Focus on HPV Vaccine Acceptance, 37 J. ADOL. HEALTH, S17-23, S18-19 (2005).
101 See Zimet, supra note 100, at S18. Despite the stigma associated with sexually-transmitted infections, empirical research has shown high interest in the HPV vaccine. Id. In a study of
A. Arguments Against a Mandatory Vaccine

Opponents of mandatory HPV vaccination for school entry contend that such mandates presuppose that young girls will engage in sexual behavior that could result in HPV contraction. In addition, a common criticism from parents in response to the pending legislation is that the requirement would infringe on their parental authority to make medical decisions for their children. Further, many parents believe that the HPV vaccine mandate could prompt conversations about sexual behavior that parents might be uncomfortable or unwilling to have with their daughters at such a young age. Some even object to the mandate based on the notion that immunizing young girls against HPV will give the girls a false sense of security and encourage promiscuity. Families with firm religious or moral beliefs in abstinence before marriage and monogamy after marriage have argued that the state legislature must respect their values and acknowledge the fact that their children might not need the HPV vaccination.

The strongest arguments against moving ahead quickly with a HPV vaccine requirement are practical and financial. Consistent with the “long-standing parental concerns about the safety of school-based vaccinations,” such as for mumps and measles, objectors to the HPV vaccine mandate are understandably apprehensive about the safety of the vaccine. Clinical trials thus far have only been conducted over five years, and, although future studies will evaluate the long-term impact of the HPV vaccine, current research has not shown how long the protection will endure or whether

young women recruited from community and clinical sites before the introduction of Gardasil, 85% of the participants indicated that they would receive an HPV vaccine for cervical cancer prevention if it became available. See Jessica A. Kahn, et al., Attitudes about Human Papillomavirus Vaccine in Young Women, 14 INT. J. AIDS, 300, 306 (2003).


See Carol Chmelynski, supra note 103.


See Gerber, supra note 5, at 496.


there might be any adverse effects on one’s health. Given the overall low prevalence of HPV types 16 and 18, the two types responsible for the majority of cervical cancer cases among women, the unknown side effects of the vaccine may prove to be more harmful than beneficial.

Critics also claim that, unlike the diseases targeted by other mandatory vaccines, such as measles, HPV does not pose a risk of rapid transmission in schools since it is not a highly infectious airborne disease. The HPV vaccination is not aimed at herd immunity; rather, the primary justification for the HPV vaccine is to protect the recipient from the long-term risks of the disease. Because HPV is not highly infectious, the rush to impose compulsory vaccination may be premature, and such mandates may be more appropriate for the future as more information on the vaccine is available.

Opponents to the mandate further argue that if states mandate the HPV vaccine for school entry, the states may face the burden of paying to immunize those girls without insurance to cover the vaccination cost. States also need to consider how they would compensate vaccine recipients if they incurred serious adverse effects in the future as a result of the vaccine that the state mandated. Also, because the prevalence of the high-risk HPV types linked to cervical cancer is low among the general population of U.S. women, adversaries to mandatory HPV vaccination claim that the costs of a widespread immunization program, as opposed to a targeted immunization program,

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109 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1921-22; see also Eileen F. Dunne & Lauri E. Markowitz, supra note 12, at 628. In 1976, though swine influenza caused only one documented death in the U.S., the influenza vaccine mandated by the U.S. government seriously injured or killed hundreds. See Sigrid Fry-Revere, The Rush to Vaccinate, N.Y. TIMES, Mar. 25, 2007, available at http://www.nytimes.com/2007/03/25/opinion/25Fry-revere.html. The vaccine caused Guillain-Barre syndrome, a rare paralytic disease similar to polio, with a 5% fatality rate and a 10% rate of permanent paralysis. Id.
110 See supra notes 38-66 (discussing findings of prevalence studies of HPV); see also Gerber, supra note 5, at 496 (noting “unintended side effects could have vast public health implications”).
111 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922.
112 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922. “Herd immunity” refers to vaccination intended to prevent immediate harm to others. Id.
113 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922.
114 See Brody, supra note 78.
115 See Lawrence O. Gostin & Catherine D. DeAngelis, supra note 76, at 1922. If a state mandates a vaccine, the state would probably complicate tort claims if some courts held that the manufacturer had no responsibility for consumer injuries. Id. A state should also consider providing a compensation system and the issues of legal liability and fair compensation. Id.
outweigh the benefits. This group believes that with the wide use of Pap testing in the U.S., the introduction of the new HPV vaccine would be insignificant in reducing cervical cancer rates.

B. Arguments for a Mandatory HPV Vaccine

The strongest argument in favor of vaccinating young girls is the potential to prevent cervical cancer and save lives. Without a mandatory vaccination, those girls and women who are unaware of, or cannot afford, the vaccine risk the infections associated HPVs, cervical cancer, and even death. Given the relatively high HPV prevalence in young women with low-risk sexual behaviors and the absence of a practical set of factors to define a high-risk group, widespread rather than targeted immunization of young women will provide a greater public health benefit against this ubiquitous infection.

Though some argue that mandatory vaccination is a usurpation of parental authority, the U.S. has a long history of similar programs. Both federal and state case law make clear that states may require people to be vaccinated and that public schools may deny access to unvaccinated children. The “constitutionality of vaccination mandates is premised on the reasonableness of the risk-benefit balance, the degree of intrusion on personal autonomy, and . . . the presence of a public health necessity.”

116 See HPV Prevalence, supra note 21, at 819. “Mandatory vaccination opponents . . . maintain that without the overwhelming public health benefits that lend credibility to traditional vaccination programs, parental rights should be paramount.” See Gerber, supra note 5, at 496.
118 See A Necessary Vaccine, supra note 107; see also supra notes 22, 23, 28 (discussing link between HPV and cervical cancer).
119 See A Necessary Vaccine, supra note 107.
120 See Manhart, supra note 35, at 504 (discussing prevalence of HPV among young women with few sexual partners).
121 See Gerber, supra note 5, at 496. All fifty states require proof of a child’s immunization before entering school, some even requiring the vaccine for the sexually transmitted infection Hepatitis B. Id. In Boone v. Boozman, the District Court of Arkansas held that the legislature did not even need to provide a religious exemption for vaccinations under the First Amendment, requiring a young girl to get a Hepatitis B immunization before she could attend school. 217 F. Supp. 2d 938, 956-957 (E.D. Ark. 2002).
122 See Charo, supra note 105, at 1906.
123 See Charo, supra note 105, at 1906.
Despite parental concerns regarding a mandatory vaccination for a sexually-transmitted disease, studies suggest only about 23% of parents are likely to deny consent for their children's HPV vaccination.124 Further, a recent study showed a high parental acceptance of a vaccine for a sexually transmitted infection ("STI"), suggesting that most parents are focused on their child's health regardless of the source of infection.125 Research has also shown that there is no significant correlation of parents' and guardians' acceptability of vaccines for STIs with the child's age, indicating that parents do not necessarily differentiate the need for STI vaccination based on their child's age.126

In addition, although opponents argue that a mandatory HPV vaccine implies that young girls face future infection, taking preventive measures for future benefits is the principle on which every immunization is based.127 Supporters of the mandate analogize the HPV vaccine to more familiar childhood vaccines, such as those against the measles, mumps, or hepatitis, and they note that, although these required vaccination programs have curtailed some parental rights, they have also significantly lowered the incidence of diseases and the number of annual deaths.128 Thus, vaccinating every adolescent female protects the few who would contract HPV and suffer its devastating consequences had the vaccination been unavailable.129

Most experts agree that the HPV vaccine will have little impact on the sexual activity of teenagers.130 Although the HPV vaccine protects against one sexually

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124 The Oncologist, supra note 117, at 395. In a study of 315 parents of children younger than eighteen years, 69% of parents indicated that they would have their child vaccinated against human herpes virus 2, an STI. See Zimet et al., Parental Attitudes About Sexually Transmitted Infection Vaccination for Their Adolescent Children, 159 ARCH. PEDIATR. ADOLESC. MED. 132, 135 (2005). In a study of 278 parents of children aged twelve to seventeen, there was a high acceptability rate of vaccinations for STIs, suggesting that most parents would not react negatively to the suggestion that their child be immunized against STIs. Id. at 136.

125 Zimet et al., supra note 124, at 136.

126 See Zimet et al., supra note 124, at 135. This finding suggests that parents might not base their decisions about vaccination on the relative temporal proximity of their children to the onset of sexual activity. Id.

127 See Brody, supra note 78, at 135. For example, not every child had contracted polio or smallpox before the enactment of mandatory vaccines for those diseases. Id.


129 Brody, supra note 78.

130 See Gerber, supra note 5, at 496. Sex education and condom distribution have not been shown to increase sexual activity among teens. See Charo, supra note 105, at 1907. In fact, abstinence-
transmitted infection, sexually active girls still risk contracting other sexually transmitted diseases, such as Chlamydia and Human Immunodeficiency Virus ("H.I.V."). There is no data to suggest that HPV vaccine would encourage adolescent girls to engage in risky sexual behavior.

To address religious or moral concerns, the majority of state proposals include exemptions for parents and guardians opposed to mandatory vaccination based on religious or secular grounds. Some states, such as Virginia, have provided an even broader exemption for the HPV vaccine allowing parents and guardians to choose against vaccinating their daughters for any reason. Alternatively, many state proposals for the mandate do not include an HPV exemption provision. Furthermore, some states are considering additional requirements to qualify for HPV vaccination exemption than is required for other school entry vaccinations.

Because the HPV vaccine targets female adolescents, and adolescents often look to their parents for guidance on vaccination issues, parental consent will most likely be

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131 Brody, supra note 78. In addition to sexually-transmitted diseases, a sexually active girl faces the risk of unwanted pregnancy. Id.
133 See Gerber, supra note 5, at 496; see also National Vaccine Information Center (NVCI), Legal Exemptions to Vaccination, available at http://www.nvic.org/state-site/legal-exemptions.htm (last visited Nov. 27, 2007). All states except Mississippi and West Virginia allow religious exceptions for mandatory vaccinations. See NVCI, supra. The religious exception is intended for those who hold a sincere religious belief opposing vaccination, such that mandatory vaccination would be an infringement on their right to exercise their religious beliefs. See NVCI, supra. Some states require the refusal to be based on an organized religion’s established tenets while other states define religious exemptions broadly to include personal or philosophical beliefs. See NVCI, supra. In many of these states, individuals must object to all vaccines, rather than specific ones, in order to use the philosophical or personal belief exemption. See NVCI, supra.
134 See Gerber, supra note 5, at 496. The Virginia law for mandatory HPV vaccination allows parents and guardians to opt of the vaccine “at the parent or guardian’s sole discretion.” Id.; H.B. 2035 ER, 2007 Leg., Reg. Sess. (Va. 2007).
135 See Gerber, supra note 5, at 496.
136 See Gerber, supra note 5. For example, in addition to the normal exemption requirements, some states’ proposed laws would require that the parent or guardian show proof that he or she reviewed information about HPV and the HPV vaccine before choosing to opt out of the vaccination. Id.
required if the vaccine is voluntary. Yet, the sexually transmitted aspect of HPV may thwart parental approval for the HPV vaccine. Parents might withhold consent for the vaccination for a variety of reasons, but if they are in denial or unaware of their daughter's sexual behavior, parents are more likely to falsely assume that their daughter is not an appropriate candidate for the HPV vaccine.

Although public health officials concede that widespread mandatory HPV vaccination will be costly, many believe the costs of HPV immunization will be lower than the current costs of HPV infections. In addition, the costs of the vaccine pale in comparison to the physical and emotional costs of HPV-induced cervical cancer to women, many of whom suffer infertility or even death as a result of HPV contraction. Moreover, the availability of data on type-specific HPV prevalence in the United States can be used as a baseline to measure the wide-scale impact of the vaccine for reducing infection. This data can also be used to ensure the cost-effectiveness of the measures for HPV vaccination implementation, such as the appropriate age group to vaccinate.

VI. The Future of the HPV Vaccine

In the excitement of the advent of the first cancer vaccine, states may have overlooked the possibility that some population groups might object to a mandatory HPV vaccine. It is difficult for some legislators, parents, public health care

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137 See Zimet, supra note 100, at S19; see also The Oncologist, supra note 117, at 395. Research on the Hepatitis B vaccine demonstrates that parental consent is a major factor in a vaccine’s acceptance. Zimet, supra note 100, at S19.
138 Zimet, supra note 100, at S19.
139 See Gerber, supra note 5, at 496.
141 See Brody, supra note 78. Cervical cancer costs in the U.S. range from $181.5 million to $363 million annually. Id.
142 HPV Prevalence, supra note 21, at 813. Published studies of the cost-effectiveness of the HPV vaccination indicate that the cost per quality-adjusted life year (QALY) saved due to vaccination against HPV types 16 and 18 would be in the $15,000 to $25,000 range per QALY. CDC, HPV and HPV Vaccine – Information for Healthcare Providers, available at http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-hcp.htm#cost-effectiveness (last visited Nov. 7, 2007). If the studies had included the benefits of preventing HPV types 6 and 11, the cost-effectiveness of vaccination would appear more favorable. Id.
143 See HPV Prevalence, supra note 21, at 813.
144 See Gerber, supra note 5.
physicians, and other interested parties to overcome the fact that HPV is a sexually transmitted disease.\textsuperscript{145} The promising clinical results regarding the efficacy of the vaccine should not obscure the ethical issues related to mandatory vaccination of young girls.\textsuperscript{146}

Many young girls are, or will become, sexually active, and the HPV vaccine, the first cancer vaccine, works best when administered before an adolescent or adult woman engages in sexual activity that puts her at risk for HPV contraction.\textsuperscript{147} Since requiring parental consent for HPV vaccination may impede many young girls from receiving the vaccine, a vaccine mandate ensures that all young girls reap the benefits of the vaccine.\textsuperscript{148} In addition, if vaccination is voluntary, a parent may choose not to vaccinate his or her daughter simply because the parent is unaware of the daughter’s sexual behavior.\textsuperscript{149} Thus, vaccinating all girls at an early age, regardless of their or their parents’ beliefs or decisions about sexual activity optimizes the HPV vaccine’s potential to protect the health of the female adolescent population.\textsuperscript{150}

The majority of proposed vaccine mandates include some type of opt-out option for parents, making the mandates suggestions for parents to vaccinate their daughters against HPV.\textsuperscript{151} Even in those states that would provide a special exemption for parents and guardians for the HPV vaccine, parents have the same religious or secular exemption rights that they have for other school-based vaccines.\textsuperscript{152} The mandates, therefore, would not infringe on parental rights any more than required school-based measles and mumps vaccinations.\textsuperscript{153}

Because parents in a majority of states have exemption rights based on religious or secular grounds, and in some cases, for any reason, objections to a mandatory vaccination seem to be based more on acknowledging teenage sexuality than on

\textsuperscript{145} See Grady, supra note 1.
\textsuperscript{146} The Oncologist, supra note 117, at 394; Markowitz et al., supra note 9 (discussing results of HPV vaccine efficacy studies).
\textsuperscript{147} Dailard, supra note 72 (discussing statistics regarding sexually active young American girls); FDA Press Release, supra note 2.
\textsuperscript{148} See Gerber, supra note 5, at 496.
\textsuperscript{149} See Gerber, supra note 5, at 496.
\textsuperscript{150} See Gerber, supra note 5, at 496.
\textsuperscript{151} See Charo, supra note 105, at 1906.
\textsuperscript{152} See supra notes 133-34 and accompanying text (discussing state vaccine legislation that includes exemptions for parents and guardians).
\textsuperscript{153} See Charo, supra note 105, at 1905-1906.
preemption of parental rights.\textsuperscript{154} Under many of the proposed mandates, the only real burden imposed on parents and guardians is the duty to actively manifest an objection to vaccinating their daughters.\textsuperscript{155} Mandatory vaccines, therefore, would not necessarily force parents and guardians to vaccinate their daughters, but rather to consider their daughters' likelihood of engaging in sexual activity, an awkward topic that might otherwise be taboo in their household.\textsuperscript{156} "[G]iven that the moral objections to requiring HPV vaccination are largely emotional, this source of resistance to mandates is difficult to justify."\textsuperscript{157}

While a mandatory HPV vaccination would impose a small burden on parents to exempt their daughters, the mandate would ensure that all young girls were at least presented with an opportunity for vaccination.\textsuperscript{158} Because a voluntary vaccination program requires affirmative action by a parent or guardian, if parents or guardians forget to opt in, children miss out on the benefits of the HPV vaccine.\textsuperscript{159} An opt-out approach, on the other hand, increases vaccination rates among children whose parents have no legitimate objection to the requirement, while still preserving parental autonomy.\textsuperscript{160}

Furthermore, if parental consent is required for HPV vaccination, many girls might risk an HPV infection rather than get parental consent.\textsuperscript{161} In weighing the consequences of revealing their sexual activity to their parents against the consequences of foregoing HPV vaccination, teenage girls may decide not to obtain parental consent for the HPV vaccine.\textsuperscript{162} Because young girls and parents alike may feel uncomfortable discussing sex, young girls for whom the vaccine is currently targeted may not fully understand the potential benefits of the HPV vaccine on their well-being until they have already been exposed to HPV.\textsuperscript{163}

\textsuperscript{154} See Charo, supra note 105, at 1905.
\textsuperscript{155} See Charo, supra note 105, at 1905.
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\textsuperscript{159} See Charo, supra note 105, at 1906.
\textsuperscript{160} See Charo, supra note 105, at 1906-1907. The proposed laws permit parents to opt out of the vaccination for their daughters, and the only burden on parents is to actively manifest such refusal. \textit{Id.} at 1907. Such a slight burden hardly justifies forgoing a means of protecting women from "the scourge of cervical cancer." \textit{Id.} In Virginia, parents do not even have to put their refusals in writing. See Charo, supra note 105, at 1907.
\textsuperscript{161} See Gerber, supra note 5, at 496.
\textsuperscript{162} See Gerber, supra note 5, at 496.
\textsuperscript{163} See Gerber, supra note 5, at 496.
The fact that the world’s first cancer vaccine has the potential to protect thousands of new cases of cervical cancer and hundreds of thousands of cases of genital warts and precancerous growths each year should not be undermined.\textsuperscript{164} Although it is true that even without HPV vaccination a young girl is likely to never develop genital warts or cervical cancer, the same is true for the majority of school-based vaccines.\textsuperscript{165} Further, because the vaccine only targets four HPV types, even a vaccinated woman may develop HPV infections or cervical cancer, and, thus, administrators need to make it clear that recipients should continue routine cervical cancer screening.\textsuperscript{166} That said, evidence suggests that, with the addition of the HPV vaccine to a women’s cervical cancer prevention regimen, fewer women will suffer from HPV infections and potentially fatal cervical cancer.\textsuperscript{167}

Further, because the vaccine is more expensive than many other vaccinations, requiring vaccination will ensure that all young girls and women have access to the vaccine, regardless of their financial situation. School-based vaccination requirements will reduce the confusion about whether or not a recipient’s insurance covers the vaccine. Further, a vaccine mandate will help to alleviate the lag time between the vaccine distribution and addition of the HPV vaccine coverage under most insurance plans that is likely to result with an ACIP-recommended vaccine.\textsuperscript{168}

Conversely, because of the relatively small amount of information currently available on the long-term safety of the HPV vaccine, states should refrain from jumping on the bandwagon to require vaccination.\textsuperscript{169} The unknown risk of adverse side effects and the amount of resulting liability states could potentially face outweighs the rush to require vaccination against a disease that is not highly contagious, nor poses an immediate risk of serious harm.\textsuperscript{170} Requiring vaccination without adequate information on the vaccine’s long-term effects is premature and unnecessarily abdicates a young girl’s and her parents’ freedom to control the young girl’s health and well-being.\textsuperscript{171} “Mandatory Gardasil vaccinations [for young girls] certainly brighten Merck’s future.”

\textsuperscript{164} See \textit{A Necessary Vaccine}, supra note 107.

\textsuperscript{165} See Manhart, supra note 35 (explaining low prevalence of HPV types 16 and 18 in women tested); see also \textit{ACS FAQs}, supra note 3 (noting that HPV infections usually clear on their own).

\textsuperscript{166} See Brody, supra note 787; see also \textit{The Oncologist}, supra note 117.

\textsuperscript{167} See \textit{The Oncologist}, supra note 1167.

\textsuperscript{168} See \textit{CDC Q&As}, supra note 9.

\textsuperscript{169} See Fry-Revere, supra note 109. Follow-up studies will help determine the duration of immunity. See \textit{FDA Press Release}, supra note 2 (discussing studies Merck has agreed to conduct following licensure).

\textsuperscript{170} See Lawrence O. Gostin \& Catherine D. DeAngelis, supra note 76, at 1923.

\textsuperscript{171} See Lawrence O. Gostin \& Catherine D. DeAngelis, supra note 76, at 1923.
but . . . it's simply not sensible policy to experiment on such a large portion of our population all at once."\textsuperscript{172}

In the face of the uncertainties regarding the HPV vaccine, parents, not state legislators, should choose whether or not to vaccinate their daughters.\textsuperscript{173} Parents and guardians should be given an opportunity to analyze available research data on the efficacy and safety of the HPV vaccine.\textsuperscript{174} Then, based on their personal understanding that the long-term effects of the vaccine are still unknown, individual families should be able to make health-risk assessments about whether or not to vaccinate their daughters.\textsuperscript{175}

Moreover, as recent studies show, the prevalence of high-risk HPV types in girls and adolescents is relatively low.\textsuperscript{176} Consequently, the impact of the vaccine in benefiting women's health may be too insignificant to justify the costs of a widespread vaccine administration. With the effectiveness of Pap testing already in use, the added costs of requiring the HPV vaccine for young girls may outweigh the added benefit of detecting and preventing HPV infections and cervical cancer.\textsuperscript{177}

For now, legislators should focus on gathering more information about the safety, efficacy, availability, and cost-effectiveness of the vaccine. As researchers gather more information on the vaccine with time, states will likely be better equipped to create mandatory vaccination measures in the future, and the public will likely be more trusting of the vaccine and the need for school-based mandates. In the meantime, states should continue to concentrate on measures to ensure that those adolescent and adult females who voluntarily elect to get vaccinated against HPV are financially and practically able to do so.

VII. Conclusion

Many state proposals to mandate the HPV vaccine have raised ethical and practical concerns. The debate centers on parental preemption, effects on the adolescent sexual behavior, efficacy and safety of the vaccine, and the economic impact

\textsuperscript{172} See Fry-Revere, supra note 109.
\textsuperscript{173} See The Oncologist, supra note 128.
\textsuperscript{174} See The Oncologist, supra note 128.
\textsuperscript{175} See Fry-Revere, supra note 109.
\textsuperscript{176} See supra notes 45 and 53 (providing high-risk HPV prevalence statistics from NHANES and ADHEALTH studies).
\textsuperscript{177} See supra notes 64-68 (discussing use and importance of Pap testing).
of a widespread vaccine mandate. The enactment of a mandatory school-based HPV vaccine in Virginia has set the model by which other states can evaluate the consequences of such a mandate. Only time will tell if other state legislators choose to follow Virginia's lead or to wait until researchers have more information about the vaccine to consider requiring HPV vaccination for school entry. Although clinical studies have shown that the HPV vaccine has immense potential to protect women against HPV infections, further studies are needed, and in fact, are required as a condition to the FDA's approval of Gardasil. Therefore, state legislatures should incorporate the HPV vaccine into their health care systems one step at a time, beginning with voluntary vaccination measures and, with time, moving onto mandatory vaccination measures that are tailored to the health and well-being of the population at risk of contracting HPV.