

## THREE SHOTS IN THE ARM: THE HPV VACCINE AND INCLUSIVE HEALTH POLICY

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### INTRODUCTION

In 2006, the Food and Drug Administration (FDA) approved a vaccine for certain strains of the human papillomavirus (HPV), the most common sexually transmitted infection (STI) in the United States.<sup>1</sup> The FDA initially approved this vaccine, Gardasil, only for use in females (age twelve through twenty-six) to prevent cervical cancer and genital warts in females caused by HPV.<sup>2</sup> Merck & Co., the vaccine manufacturer, marketed it to adolescent females and parents with adolescent daughters as a means of preventing cervical cancer. In 2009, the FDA approved the use of Gardasil in males for the prevention of genital warts.<sup>3</sup> Although males and females are equally susceptible to HPV, and equally likely to transmit the disease to a sexual partner, the focus on cervical cancer prevention precludes the inclusion of males in HPV vaccine media campaigns and health policies. The concentration on cervical cancer overshadows discussions of other cancers prevented by the vaccine, and stymies the development of comprehensive HPV

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<sup>1</sup> Gardiner Harris, *U.S. Approves Use of Vaccine for Cervical Cancer*, N.Y. TIMES, June 9, 2006, at A1.

<sup>2</sup> *Id.*

<sup>3</sup> *FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance From the Advisory Committee on Immunization Practices*, 304 JAMA 518, 518 (2010) [hereinafter *FDA Licensure of HPV Vaccine*].

vaccination policies.

State-mandated vaccinations for school attendance are the most effective means of vaccinating a population. Supreme Court doctrine supports this policy.<sup>4</sup> However, in the case of HPV, there are impediments to a comprehensive vaccination requirement. Three themes appear in arguments against HPV vaccinations: (1) legality; (2) vaccine safety; and (3) adolescent sexuality. First, opponents question the constitutionality of an HPV vaccination mandate because HPV is not an airborne disease, as are those targeted by most mandated vaccinations. The means of a disease's transmission, however, does not impact its legal analysis, and the Hepatitis B vaccine is a prime example of a mandated vaccination for a sexually transmitted disease. Additionally, many oppose such legislation because a required vaccination impinges on parental autonomy. Although the Supreme Court supports parental autonomy in the upbringing of children,<sup>5</sup> this privilege is not without limit.<sup>6</sup> A state's right to mandate a vaccination necessarily infringes on parental autonomy, and is supported by legal precedent because parents are not allowed to subject their children to harm.<sup>7</sup> Second, opponents question the vaccine's long-term health effects and its general safety. Medical research, though, supports the vaccine's safety for both males and females, and there have been almost no serious adverse events associated with the vaccine.<sup>8</sup> Finally, opponents argue that mandating such a vaccination will increase sexual activities by giving adolescents a false sense of security about sex, as well as undercut efforts made by abstinence-only education.<sup>9</sup> These are the two most prominent arguments against the vaccine, but nevertheless also fail. Other cornerstones of safe sex education, like the promotion of condoms and emergency contraception, have neither increased sexuality activities, nor undercut efforts by abstinence-only education.<sup>10</sup> As this Article will demonstrate, the arguments attacking the vaccine are flawed, and serve only as impediments to its widespread use.

HPV vaccination conversations need to be shifted away from discussions of adolescent sexuality, and policies need to include both males and females. This Article argues that focusing HPV vaccination efforts on females is a mistake with serious health policy consequences. First, vaccines that target only one segment of the population are not effective at reducing the prevalence of a communicable disease. Second, current vaccination policies center on heterosexual transmission of the disease, and thus these policies are exclusivist and ignore men who have sex with men, a high-risk subgroup for HPV and HPV-related infections, as well as

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<sup>4</sup> See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>5</sup> See *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534–35 (1925) (asserting that *Meyer v. Nebraska* stands for the doctrine that parents have the liberty to “direct the upbringing and education of [their] children . . . .”); see also *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972) (“This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition.”).

<sup>6</sup> *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944).

<sup>7</sup> *Id.*

<sup>8</sup> See *infra* notes 166–183 for more on the safety and long-term efficacy of the HPV vaccine.

<sup>9</sup> Lane Wood, *A Young Vaccine for Young Girls: Should the Human Papillomavirus Vaccination Be Mandatory for Public School Attendance?*, 20 *THE HEALTH LAW* 30, 34 (2007–2008); see also Nancy Gibbs, *Defusing the War over the “Promiscuity” Vaccine*, *TIME*, June 21, 2006, <http://www.time.com/time/nation/article/0,8599,1206813,00.html>.

<sup>10</sup> See generally Bradley J. Monk & Dorothy J. Wiley, *Will Widespread Human Papillomavirus Prophylactic Vaccination Change Sexual Practices of Adolescent and Young Adult Women in America?*, 108 *OBSTETRICS & GYNECOLOGY* 420 (2006); see also Amy Bleakley et al., *Public Opinion on Sex Education in US Schools*, 160 *ARCHIVE OF PEDIATRIC & ADOLESCENT MED.* 1151 (2006).

women who have sex with women.<sup>11</sup> Additionally, current vaccination policies fail to reach low-income females, who are disparately impacted by HPV and HPV-related cancers. Instead of focusing exclusively on females, vaccination efforts need to be directed at both males and females. State-mandated vaccinations for school attendance reduce disease occurrence and are a legal means of creating population-wide immunity. To ensure maximum coverage, accessibility, and immunity, this Article calls for an HPV vaccination requirement for school attendance for both adolescent males and females.

This Article is divided into three parts. Part I examines HPV, the infections caused by the virus, and the incidence of HPV-related diseases in the United States. This section also discusses the efficacy of the HPV vaccine. Part II provides reasons for comprehensive vaccination policies through an examination of the population subgroups ignored by current vaccination policies. This section examines theories of population (herd) immunity, and speaks to the issue of whether comprehensive HPV vaccination policies are cost-effective. Part III argues that mandating the HPV vaccination for male and female adolescents for school attendance is constitutional and the best way to ensure effective vaccine coverage and adherence. This Article brings together a variety of issues surrounding the current HPV vaccine controversy in order to demonstrate that the vaccine is an important health intervention. A school mandate will ensure a sex-neutral and sexuality-neutral approach to eradicating HPV-related cancers and genital diseases.

## I. THE HUMAN PAPILLOMAVIRUS

### A. *Human Papillomavirus & Cancer*

Human papillomavirus is the most common sexually transmitted infection (STI) in the United States,<sup>12</sup> infecting over 20 million people.<sup>13</sup> HPV is transmitted through sexual contact, typically during vaginal and anal sex, but can also be transmitted through oral sex and genital-to-genital contact (i.e. skin to skin contact).<sup>14</sup> According to the National Cancer Society, the only way to prevent HPV transmission is by abstaining from all sexual activity; more realistically, having sexual contact with fewer partners or with people who do not have a lot of sexual partners lowers the risk of HPV infection.<sup>15</sup> Condoms are helpful in the prevention of HPV,<sup>16</sup> but because

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<sup>11</sup> In this article, the terms male and female refer to biological sexes, not genders. I avoid the use of the term “homosexual” in favor of MSM and WSW because the latter terms are commonly used in medical and public health discourse.

<sup>12</sup> *Human Papillomavirus (HPV)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hpv/> (last visited Apr. 10, 2012).

<sup>13</sup> *Genital HPV Infection – Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last visited Apr. 10, 2012)

<sup>14</sup> *Id.*

<sup>15</sup> *Human Papilloma Virus (HPV), Cancer, and HPV Vaccines: Frequently Asked Questions*, AM. CANCER SOC’Y, <http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/InfectiousAgents/HPV/HumanPapillomaVirusandHPVvaccinesFAQ/hpv-faq-how-common-is-hpv#top> (last updated Mar. 22, 2012) [hereinafter *HPV FAQs*, AM. CANCER SOC’Y].

<sup>16</sup> Marcia L. Shew et al., *Association of Condom Use, Sexual Behaviors, and Sexually Transmitted Infection with the Duration of Genital Human Papillomavirus Infection Among Adolescent Women*, 160 ARCHIVES OF PEDIATRIC & ADOLESCENT MED. 151, 155 (2006).

it can be passed from genital-to-genital contact the disease can be transmitted prior to condom usage.<sup>17</sup> Cases of HPV are most prevalent in females in their early twenties, and then tend to decrease with age.<sup>18</sup> By contrast, HPV incidence in males is consistent across age ranges; about sixty percent of males between the ages of eighteen and seventy have HPV in the United States.<sup>19</sup>

There are over one hundred strains of HPV,<sup>20</sup> and about forty of these strains infect the genital area.<sup>21</sup> Ninety percent of cases of HPV infection clear up within two years.<sup>22</sup> However, strains six, eleven, sixteen, and eighteen are considered high-risk because they cause genital diseases, including cancers and genital warts.<sup>23</sup> Strains sixteen and eighteen cause seventy percent of all cases of cervical cancer and a significant number of cases of anal, vulva, vaginal, penile, and throat, head and neck cancers.<sup>24</sup> Additionally, strains six and eleven cause about ninety percent of all cases of genital warts.<sup>25</sup> Genital warts and cervical cancer are the two most common conditions associated with HPV.<sup>26</sup>

Approximately five percent of all cancers worldwide are caused by HPV.<sup>27</sup> There is consensus in research and medical communities that HPV not only causes cervical cancer, but is responsible for nearly all cases of cervical cancer.<sup>28</sup> According to the American Cancer Society, in 2010 there were 12,200 women who developed new cases of cervical cancer and 4,210 women who died from cervical cancer.<sup>29</sup> The occurrence rate for cervical cancer is 8.1 per 100,000 females, on average, in the United States.<sup>30</sup> The death rate for cervical cancer is relatively low: 2.4 out of 100,000 females with the disease die from it.<sup>31</sup> Regular pap smears, a routine procedure that tests for irregular cells on the cervix, have been effective in catching cancerous cells on the

<sup>17</sup> HPV FAQs, AM. CANCER SOC'Y, *supra* note 15, at 4.

<sup>18</sup> See Micah Globerson, *Protecting Women: A Feminist Legal Analysis of the HPV Vaccine*, 17 TEX. J. WOMEN & L. 67, 69–70 (2007); Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1733 (2008).

<sup>19</sup> Shari Roan, *HPV: Men Can Get it Too*, L.A. TIMES, Mar. 19, 2007, at F1; see also ANNA R. GIULIANO ET AL., INCIDENCE AND CLEARANCE OF GENITAL HUMAN PAPILLOMAVIRUS INFECTION IN MEN (HIM): A COHORT STUDY 6 (2011) [hereinafter GIULIANO ET AL., INCIDENCE AND CLEARANCE] (asserting that: “Whereas risk of HPV decreases with increasing age in women, men seem to have a stable risk for acquiring new HPV infections throughout their life.”).

<sup>20</sup> Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J. L. MED. & ETHICS 384, 385 (2008).

<sup>21</sup> *Genital HPV Infection – Fact Sheet*, *supra* note 13.

<sup>22</sup> *Id.*

<sup>23</sup> Javitt et al., *supra* note 20, at 385.

<sup>24</sup> *Id.*; see also Hisham Mehanna et al., *Head and Neck Cancer – Part I: Epidemiology, Presentation, and Prevention*, 341 BRIT. J. MED. 663, 664 (2010) [hereinafter Mehanna et al., *Head and Neck Cancer*].

<sup>25</sup> Javitt et al., *supra* note 20, at 385.

<sup>26</sup> *Genital HPV Infection – Fact Sheet*, *supra* note 13.

<sup>27</sup> Anil K. Chaturvedi, *Beyond Cervical Cancer: Burden of Other HPV-Related Cancers Among Men and Women*, 46 J. ADOLESCENT HEALTH S20, S20 (2010).

<sup>28</sup> *Id.* at S21; see also HPV FAQs, AM. CANCER SOC'Y, *supra* note 15, at 4.

<sup>29</sup> AM. CANCER SOC'Y, CANCER FACTS AND FIGURES 2010 4 (2010), available at <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-026238.pdf> [hereinafter CANCER FACTS AND FIGURES].

<sup>30</sup> *SEER Stat Fact Sheet: Cervical Uteri*, NAT'L CANCER INST., <http://www.seer.cancer.gov/statfacts/html/cervix.html> (last visited Apr. 10, 2012).

<sup>31</sup> *Id.*

cervix at an early stage and preventing the development of cervical cancer.<sup>32</sup> Some argue that there is no need for a vaccine, because regular exams and screenings, when available, are effective, less costly, and do not involve shots.<sup>33</sup>

Although pap smears are effective at preventing cervical cancer, they do not screen for all cancers caused by HPV infection, and the rates and prevalence of these other cancers are not insignificant. HPV causes eighty to ninety percent of anal cancers, which is a growing problem in the United States, affecting males and females alike. Between 1994 and 2000, anal cancer occurrence increased for both males and females.<sup>34</sup> In 2010, there were an estimated 5,000 new cases of anal cancer in the United States: 2,000 new cases among males, and 3,000 among females.<sup>35</sup> The incidence rate is 1.6 per 100,000 males and females per year.<sup>36</sup> The death rate from anal cancer is 0.2 per 100,000 individuals, both males and females.<sup>37</sup> Females who have HPV-related cervical or vulva cancer are at a higher risk for anal cancer because of previous exposure to cancerous HPV infection.<sup>38</sup> Most cases of anal cancer are found in men who have sex with men (MSM) and in females who have sex with males. However, studies show that there is a growing presence of anal cancer among males who have sex with females, which raises questions about how this particular disease develops once HPV is transmitted.<sup>39</sup>

In addition to cervical and anal cancer, HPV also causes an estimated forty to sixty-four percent of vaginal cancer cases, and forty to fifty-one percent of vulva cancer cases in females.<sup>40</sup> In 2010, there were an estimated 2,300 new cases of vaginal cancer and 3,900 new cases of vulva cancer.<sup>41</sup> For vulva cancer, there is an occurrence rate of 2.4 per 100,000 females in the United States, and a death rate of approximately 0.5 per 100,000 females.<sup>42</sup> The National Cancer Institute does not compile occurrence data on vaginal cancer because it is considered a rare cancer. HPV also causes thirty-six to forty percent of penile cancer cases.<sup>43</sup> In 2010, there were an estimated 1,250 new cases of penile cancer in the United States. Finally, HPV has also been found to cause throat, head and neck cancers.<sup>44</sup> Of the 49,200 new cases of throat cancer in the

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<sup>32</sup> Chaturvedi, *supra* note 27, at S23; *see also* Eliav Barr et al., *Impact of a Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) L1 Virus-Like Particle Vaccine in a Sexually Active Population of North American Women*, 198 AM. J. OBSTETRICS & GYNECOLOGY 261.e1, 261.e1 (2008).

<sup>33</sup> Judy Peres, *Who Should Get the HPV Vaccine? Usage Expands Amid Debate*, 102 J. NAT'L CANCER INST. 838, 840 (2010).

<sup>34</sup> Djenaba A. Joseph et al., *Understanding the Burden of Human Papillomavirus Associated Anal Cancers in the United States*, 113 CANCER 2892, 2892–93 (2008); *see generally*, Lisa G. Johnson et al., *Anal Cancer Incidence and Survival: The Surveillance, Epidemiology, and End Results Experience, 1973 – 2000*, 101 CANCER 281 (2004) (explaining trends in the incidence of anal cancer for various groups over time).

<sup>35</sup> CANCER FACTS AND FIGURES, *supra* note 29, at 4.

<sup>36</sup> *SEER Stat Fact Sheet: Cervical Uteri*, *supra* note 30.

<sup>37</sup> *Id.*

<sup>38</sup> Joseph et al., *supra* note 34, at 2893.

<sup>39</sup> Alan G. Nyitray et al., *Prevalence of and Risk Factors for Anal Human Papillomavirus Infection in Men who have Sex with Women: A Cross National Study*, 201 J. INFECTIOUS DISEASES 1498, 1504 (2010).

<sup>40</sup> Chaturvedi, *supra* note 27, at S21 (citing studies conducted in 2006 and 2008).

<sup>41</sup> CANCER FACTS AND FIGURES, *supra* note 29, at 4.

<sup>42</sup> *SEER Stat Fact Sheet: Cervical Uteri*, *supra* note 30.

<sup>43</sup> Nyitray et al., *supra* note 39, at 1504.

<sup>44</sup> *See generally* Gypsyamber D'Souza et al., *Case-Control Study of Human Papillomavirus and Oropharyngeal Cancer*, 356 NEW ENG. J. MED. 1944 (2007) (finding a strong association between oral HPV infection and

United States in 2010,<sup>45</sup> HPV caused about twelve to sixty percent.<sup>46</sup> According to the British Journal of Medicine, head and neck cancer is the sixth most prevalent cancer in the world.<sup>47</sup> Incidences of these cancers are increasing in the United States, and researchers attribute this increase to HPV.<sup>48</sup>

In addition to cancer, high-risk strains of HPV also cause genital warts.<sup>49</sup> Every year in the United States, about 500,000 people acquire genital warts<sup>50</sup> and ninety percent of all cases of genital warts are attributed to HPV infection.<sup>51</sup> Genital warts afflict both males and females, but typically have a longer duration of infection in males.<sup>52</sup> Although the medical effects of genital warts are relatively limited, many doctors cite the psychological affects, such as stress and embarrassment, as more serious consequences of the disease.<sup>53</sup> Recurrence of genital warts is also quite common.<sup>54</sup> Additionally, the HPV strains that cause genital warts can also lead to recurrent respiratory papillomatosis (RRP), a disease that can restrict airways and result in multiple surgeries.<sup>55</sup>

Not surprisingly, because cervical cancer is the most significant consequence of HPV, HPV is viewed as a female problem, and specifically a heterosexual female problem.<sup>56</sup> Males are typically perceived as transmitters of the infection who increase the cervical cancer risk in females, but they are not perceived as personally at risk.<sup>57</sup> This perception is incorrect. While the majority of males who contract HPV are asymptomatic, HPV does lead to negative health

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cancer of the throat).

<sup>45</sup> CANCER FACTS AND FIGURES, *supra* note 29, at 4.

<sup>46</sup> Chaturvedi, *supra* note 27, at S21. The statistics for throat cancer are harder to determine because of the other risk factors associated with the disease, including tobacco inhalation and alcohol consumption, can also be present. CANCER FACTS AND FIGURES, *supra* note 29, at 17. Additionally, researchers found that HPV-related neck and head cancer are significantly different than other types of these cancers. *See* Mehanna et al., *Head and Neck Cancer*, *supra* note 24, at S21 (“HPV related oropharyngeal carcinoma is a distinct disease entity. Patients are younger (usually 40-50 years old), often do not report the usual risk factors of smoking or high alcohol intake, and often present with a small primary tumour and large neck nodes.”).

<sup>47</sup> Hishman M. Mehanna, *Oropharyngeal Carcinoma Related to Human Papillomavirus*, 340 BRIT. J. MED. 879, 879 (2010) [hereinafter Mehanna, *Oropharyngeal Carcinoma*].

<sup>48</sup> *Id.*

<sup>49</sup> Anna R. Giuliano et al., *Epidemiology and Pathology of HPV Disease in Males*, 117 GYNECOLOGIC ONCOLOGY S15, S15 (2010) [hereinafter Giuliano et al., *Epidemiology of HPV*].

<sup>50</sup> Jan Hoffman, *Vaccinating Boys for Girls’ Sake?*, N.Y. TIMES, Feb. 24, 2008, at ST1, ST10.

<sup>51</sup> *Sexually Transmitted Disease Treatment Guidelines 2010 – Genital Warts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/treatment/2010/genital-warts.htm> (last visited Apr. 10, 2012).

<sup>52</sup> Anna R. Giuliano, *Human Papillomavirus Vaccination in Males*, 170 GYNECOLOGIC ONCOLOGY S24, S25 (2007) [hereinafter Giuliano, *HPV Vaccination*].

<sup>53</sup> Hoffman, *supra* note 50, at ST10; *see also* Giuliano et al., *Epidemiology of HPV*, *supra* note 49, at S15.

<sup>54</sup> Giuliano et al., *Epidemiology of HPV*, *supra* note 49, at S15.

<sup>55</sup> Gregory D. Zimet, *Potential Barriers to HPV Immunization: From Public Health to Personal Choice*, 35 AM. J. L. & MED. 389, 389 (2009) [hereinafter Zimet, *Potential Barriers*].

<sup>56</sup> *See infra* notes 91–102 for data on HPV and HPV-related diseases among women who have sex with women.

<sup>57</sup> Joel M. Palefsky, *Human Papillomavirus-Related Disease in Men: Not Just a Women’s Issue*, 46 J. ADOLESCENT HEALTH S12, S12 (2010).

consequences in males, including anal, penile, and throat cancers, and genital warts.<sup>58</sup> HPV in males, because it is mostly undetected and thus untreated, can weaken immune systems, and some data suggests that it makes affected males more susceptible to HIV.<sup>59</sup> HPV is particularly problematic in the MSM population, whose members are seventeen times more likely to contract HPV than males who only have sex with females.<sup>60</sup> The risk of developing HPV-related diseases is also significantly higher in this segment of the male population.<sup>61</sup>

HPV is widely assumed to be a relatively harmless STI. However, the high-risk strains of the disease are not. HPV is a serious public health issue. The HPV vaccine offers an avenue for cancer and disease reduction, and thus should be used with more frequency to prevent the spread of the high-risk strains of HPV.

### B. *The HPV Vaccine: Quadrivalent Gardasil*

In June 2006, the Food and Drug Administration (FDA) approved Merck's Gardasil, a quadrivalent HPV vaccine that protects against strains six, eleven, sixteen, and eighteen of HPV for the prevention of cervical cancer and genital warts in females only.<sup>62</sup> For females, studies from drug trials showed that the quadrivalent vaccine significantly reduced the occurrence of genital cancerous lesions and genital warts.<sup>63</sup> In some studies, the vaccine was proven nearly 100% effective in preventing the genital diseases associated with HPV in females.<sup>64</sup> In October 2009, the FDA approved Cervarix, a bivalent HPV vaccine manufactured by GlaxoSmithKline Biologicals, for use in females for the prevention of cervical cancer caused by HPV strains sixteen and eighteen.<sup>65</sup> Although this Article's arguments and conclusions are relevant for Cervarix, this Article will focus on Gardasil, the quadrivalent vaccine, for two main reasons: (1) most of the clinical research has been conducted on the quadrivalent vaccine; and (2) as of February 2012, Cervarix has not yet been approved for use in males.

In October 2009, the FDA approved Gardasil for males, aged nine through twenty-six, for the prevention of genital warts caused by HPV strains six and eleven.<sup>66</sup> In drug trials on males, the quadrivalent vaccine demonstrated high levels of efficacy in reducing the occurrence of

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<sup>58</sup> *HPV & Men – Fact Sheet*, CTRES. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/hpv/stdfact-hpv-and-men.htm> (last visited Apr. 10, 2012) [hereinafter CDC, *HPV & Men*].

<sup>59</sup> Palefsky, *supra* note 57, at S12 (“[R]ecent data suggests that HPV infection in men may increase the risk of acquiring human immunodeficiency virus (HIV) infection.”). HPV is also a serious health problem for HIV-positive individuals. However, this article focuses only on HIV-negative segments of the population.

<sup>60</sup> See CDC, *HPV & Men*, *supra* note 58.

<sup>61</sup> See Jane J. Kim, *Targeted Human Papillomavirus Vaccine of Men Who Have Sex with Men in the USA: a Cost-Effectiveness Modelling Analysis*, 10 LANCET INFECTIOUS DISEASES 845 (2010) (discussing the risks of anal cancer, developed from HPV, in MSM) [hereinafter Kim, *Targeted HPV Vaccine*].

<sup>62</sup> See Harris, *supra* note 1; see also GARDASIL, <http://www.gardasil.com/> (last visited Apr. 10, 2012).

<sup>63</sup> Barr et al., *supra* note 32, at 261.e1 (2008) (describing studies conducted on North American women); see also Suzanne M. Garland et al., *Quadrivalent Vaccine Against Human Papillomavirus to Prevent Anogenital Diseases*, 356 NEW ENG. J. MED. 1928, 1935 (2007) (describing studies conducted on women across the world).

<sup>64</sup> Garland et al., *supra* note 63, at 1935.

<sup>65</sup> Press Release, Food & Drug Admin., FDA Approves New Vaccine for Prevention of Cervical Cancer (Oct. 16, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187048.htm> (last visited Apr. 10, 2012).

<sup>66</sup> *FDA Licensure of HPV Vaccine*, *supra* note 3, at 518.

genital cancerous lesions and genital warts.<sup>67</sup> Although the vaccine did have lower rates of efficacy in males than in females, it was shown to reduce the rate of HPV infection in males by sixty-five percent.<sup>68</sup> While early approvals of the use of Gardasil were based on its use to help prevent cervical cancer in females and genital warts in males, it is now recognized as efficacious in preventing anal cancer as well. In December 2010, the FDA approved Gardasil for the prevention of anal cancer in both sexes.<sup>69</sup>

The use of Gardasil is strongly supported by federal agencies. The Advisory Committee on Immunization Practices (ACIP), which advises the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS), recommended the administration of the vaccine for both males and females. The ACIP is a crucial part of state and federal vaccination policies. The ACIP is an external, non-partisan group, made up of fifteen medical experts not employed by the United States government, that issues policy recommendations to the CDC and HHS.<sup>70</sup> The ACIP was formed in 1964 to provide outside expert advice and guidance to the CDC and HHS on the use of vaccines in civilian populations.<sup>71</sup> ACIP recommendations dictate national vaccination policy and play an essential role in the control of contagious diseases in the United States. ACIP recommendations reach beyond the federal government, and are largely followed by states in determining vaccination policies.<sup>72</sup> In 2009, the ACIP recommended routine administration of the HPV vaccine for females. When the ACIP first approved the HPV vaccine for males, the group gave a somewhat “lesser” recommendation for males, while still asserting that the vaccine may be given to males.<sup>73</sup> However, in October 2011, the ACIP changed their recommendation, and now recommends routine administration of the HPV vaccine for boys.<sup>74</sup> The ACIP advocated for the availability of Gardasil to males and females through Vaccines for Children,<sup>75</sup> a federal program that funds routine vaccinations for children who are unable to afford the vaccine.<sup>76</sup>

As discussed previously, the HPV vaccine is effective in preventing HPV and helping to avoid HPV-related health conditions. For the vaccine to be the most effective, however, it must

<sup>67</sup> Anna R. Giuliano et al., *Efficacy of Quadrivalent HPV Vaccine against HPV Infection and Disease in Males*, 364 NEW ENG. J. MED. 401, 409 (2011) [hereinafter Giuliano, *HPV Vaccine in Males*].

<sup>68</sup> *Id.*

<sup>69</sup> Press Release, Food and Drug Admin., FDA: Gardasil Approved to Prevent Anal Cancer (Dec. 22, 2010) available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm237941.htm>; see also Jane J. Kim, *Weighing the Benefits and Costs of HPV Vaccination of Young Men*, 364 NEW ENG. J. MED. 393, 394 (2011) (exploring the societal and health cost and benefits of providing the HPV vaccine to young men).

<sup>70</sup> Jean C. Smith et al., *Immunization Policy Development in the United States: The Role of the Advisory Committee on Immunization Practices*, 150 ANNALS INTERNAL MED. 45, 45 (2009).

<sup>71</sup> *Id.*

<sup>72</sup> Amber Oleson, *Legislative Update: Should the Human Papillomavirus Vaccine be Mandated for Pre-Adolescent Girls? The HPV Vaccine Becomes a Political Issue*, 28 CHILD. LEGAL RTS. J. 64, 66 (2008).

<sup>73</sup> *FDA Licensure of HPV Vaccine*, *supra* note 3, at 518.

<sup>74</sup> Gardiner Harris, *Panel Endorses HPV Vaccine for Boys of 11*, N.Y. TIMES, Oct. 26, 2011, at A1.

<sup>75</sup> N. Liddon et al., *Provider Attitudes Towards HPV Vaccines for Males*, 47 J. ADOLESCENT HEALTH 1, 1 (2010); see also Lauri E. Markowitz et al., *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MORBIDITY & MORTALITY WEEKLY REPORT 1, 16 (2007), available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s\\_cid=rr5602a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s_cid=rr5602a1_e).

<sup>76</sup> *Vaccines for Children Program*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/programs/vfc/default.htm> (last visited Apr. 10, 2011).



be administered before any HPV exposure.<sup>77</sup> As a prophylactic drug, and not a therapeutic one, Gardasil is only effective in preventing certain strains of HPV, and not treating them once acquired.<sup>78</sup> Due to the time sensitive nature of Gardasil, many argue it should be mandated to ensure timely adherence.<sup>79</sup> Additionally, it is argued that the focus of any HPV vaccination policies should be on adolescents to ensure that they are immunized prior to HPV exposure. The next section of this Article demonstrates why both males and females need to be included in any routine, comprehensive vaccination policy in order to better immunize the population against the high-risk strains of HPV.

## II. WHY AN INCLUSIVE HPV VACCINATION POLICY IS NECESSARY

Current HPV vaccination policies are exclusive and woefully ineffective. At the moment, the HPV vaccine administration targets only females and has not reduced occurrences of HPV across the population. The narrow focus of HPV vaccination policies on females is problematic because the vaccine is not achieving desired population-level immunity. This ineffectiveness stems from the fact that these policies explicitly fail to include all males, specifically men who have sex with men, and implicitly exclude certain subgroups of females, including low-income females and women who have sex with women. This section examines the problems with current vaccination policies by highlighting the exclusion of certain subgroups of the population, and by discussing concepts of population-wide immunity and the failures of other vaccines that targeted only certain segments of the population. This section will demonstrate why comprehensive and inclusive vaccination programs that target all members of the population will be the most effective means of reducing the occurrence of HPV and HPV-related cancers in the United States.

### A. Ignored Subgroups

Current vaccination policies fail to include three particular subgroups of the population: men who have sex with men (MSM); women who have sex with women (WSW); and low-income women, particularly those of color. MSM and WSW are both excluded from current vaccination policies because of the focus of such policies on the heterosexual transmission of the disease. Although MSM are a high-risk population for HPV, there are many barriers to successful administration of the vaccine without a formal vaccination mandate. Dr. Jane Kim of the Harvard School for Public Health argues that “[s]everal obstacles challenge early uptake in this high-risk subgroup, including age at which people self-identify as MSM [and] willingness to disclose sexual identity to others,”<sup>80</sup> all of which prevent the administration of the vaccine prior to HPV exposure. The fact that this vaccine is one that must be requested further places the HPV vaccine out of reach for many low-income women because of the lack of comprehensive reproductive health services available to this population. Thus, as is evidenced by this section, a sexuality-neutral vaccination policy, accompanied with easy accessibility, is essential for the success of the HPV vaccine.

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<sup>77</sup> HPV FAQs, AM. CANCER SOC’Y, *supra* note 15, at 8–9.

<sup>78</sup> Wood, *supra* note 9, at 31.

<sup>79</sup> Law, *supra* note 18, at 1764 (“[Y]oung people are far more likely to receive a timely vaccination prior to contracting the virus if vaccination is mandatory.”).

<sup>80</sup> Kim, *Targeted HPV Vaccine*, *supra* note 61, at 850.

### 1. Men Who Have Sex with Men

The current focus on females for the administration of the HPV vaccine completely ignores an entire population of men who have sex with men. MSM have a higher risk for HPV-related genital warts and anal cancer compared to males who only have sex with females.<sup>81</sup> MSM also have a greater risk for anal cancer than the population in general.<sup>82</sup> The risk and prevalence of anal cancer in the MSM population is arguably higher than cervical cancer for females in the United States.<sup>83</sup> Although this can be attributed to the high prevalence of vaginal pap smears and cervical cancer screenings for females,<sup>84</sup> and the relative lack of anal pap smears for males,<sup>85</sup> it highlights the dangers of HPV-related cancers for males in this subgroup. Additionally, unlike incidences of cervical cancer, which tend to decrease as females age, incidences of anal cancer remain constant throughout the sexual lifespan of MSM.<sup>86</sup>

Mandating the vaccination is the most effective and efficient means of protecting the MSM subgroup because the mere availability of the vaccine will not ensure appropriate use for this segment of the population. Many studies show that MSM do not openly admit their sexual preferences until almost two years after their first sexual contact and after having a number of sexual partners.<sup>87</sup> This affects the efficacy of administering the vaccine to MSM because the drug must be administered prior to exposure to HPV for maximum effectiveness.<sup>88</sup> Targeting this subgroup for voluntary vaccination would be futile because the drug needs to be administered prior to exposure, and would be ineffective, and a waste of resources, to administer the vaccine to a population that has already been exposed to HPV.<sup>89</sup> One researcher for the National Cancer Institute argued that the vaccine should be offered to all males because “it’s impossible to know which preadolescent boys will grow up to become men who have sex with men, [and thus] it would not be feasible to target the vaccine to that subgroup of males.”<sup>90</sup>

### 2. Women Who Have Sex with Women

Discourse around female sexual health focuses on heterosexual females, and there is documented evidence that WSW do not receive the same level of sexual health care as

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<sup>81</sup> CDC, *HPV & Men*, *supra* note 58; *see also* Paul L. Reiter et al., *Acceptability of HPV Vaccine Among a National Sample of Gay and Bisexual Men*, 37 SEXUALLY TRANSMITTED DISEASES 197, 197 (2010).

<sup>82</sup> Reiter et al., *supra* note 81, at 197.

<sup>83</sup> Marian Pitts et al., *What do Gay Men Know About Human Papillomavirus? Australian Gay Men’s Knowledge and Experience of Anal Cancer Screening and Human Papillomavirus*, 34 SEXUALLY TRANSMITTED DISEASES 170, 170 (2007). Although Pitts’ data focuses on Australia, the main ideas of her article are applicable to the United States as well because of Australia’s status as a Western country that regularly employed vaginal pap smears and cervical cancer screenings for females.

<sup>84</sup> Chaturvedi, *supra* note 27, at S23; *see also* Barr et al., *supra* note 32, at 261.

<sup>85</sup> Pitts et al., *supra* note 83, at 171–72.

<sup>86</sup> Peter V. Chin-Hong et al., *Age-Related Prevalence of Anal Cancer Precursors in Homosexual Men: The EXPLORE Study*, 97 J. NAT’L CANCER INST. 896, 904 (2005).

<sup>87</sup> D. Simatherai et al., *What Men Who Have Sex With Men Think About the Human Papillomavirus Vaccine*, 85 SEXUALLY TRANSMITTED INFECTION 148, 149 (2009).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> Peres, *supra* note 33, at 840.

heterosexual females. Feminist scholars posit “medicine constitutes a particularly powerful instrument of support for the coercive institution of heterosexuality.”<sup>91</sup> Sexual health policies typically focus on heterosexual females, and the heterosexual transmission of STIs. There are an estimated 2.3 million females in the United States who self-identify as WSW.<sup>92</sup> Sex between females is typically viewed as safer, and thus, WSW do not typically view themselves as at risk for HPV.<sup>93</sup> However, studies demonstrate that WSW do have similar risk levels for, and incidences of, HPV and cervical cancer as heterosexual females.<sup>94</sup> About thirteen percent of WSW are infected with some strain of HPV.<sup>95</sup> HPV can be transmitted through oral and vaginal sex between females, particularly when sex toys are shared.<sup>96</sup> Additionally, studies have shown that HPV is transmitted from skin-to-skin contact so that penetration is not a necessary act for acquiring the disease.<sup>97</sup> One study asserted that it is a “popular misconception that lesbians are at a decreased risk for cervical cancer compared to heterosexual women.”<sup>98</sup> Because of this misconception, there are fewer WSW who get yearly pap smears,<sup>99</sup> and thus such females are more at risk for cervical cancer because pap smears are proven to be effective at catching the disease early. Scholars argue that WSW “often avoid accessing health care because of real or perceived homophobia and heterosexism . . . [t]herefore, routine screenings are not performed and cancers may be detected at later, less treatable stages.”<sup>100</sup> Medical professionals assert that WSW need to be encouraged to have regular pap smears, just as heterosexual females are encouraged to do so yearly.<sup>101</sup> Genital warts can also affect the WSW subgroup; however, the prevalence of this infection is significantly lower than among heterosexual females and males, and the MSM subgroup.<sup>102</sup> By creating vaccination policies that are universal and sex- and sexuality-neutral,

<sup>91</sup> Virginia Braun & Nicola Gavey, “Bad Girls” and “Good Girls”?: *Sexuality and Cervical Cancer*, 22 *WOMEN’S STUD. INT’L FORUM* 203, 209 (1999) (citing SUSAN SHERWIN, *NO LONGER PATIENT: FEMINIST ETHICS AND HEALTH CARE* 213 (1992)).

<sup>92</sup> Jeanne M. Marrazzo & Kathleen Stine, *Reproductive Health History of Lesbians: Implications for Care*, 190 *AM. J. OBSTETRICS & GYNECOLOGY* 1298, 1298 (2004).

<sup>93</sup> Lisa Eaton et al., *Perceived Prevalence and Risks for Human Papillomavirus (HPV) Infection among Women Who Have Sex with Women*, 17 *J. WOMEN’S HEALTH* 75, 80 (2008).

<sup>94</sup> See generally Jeanne M. Marrazzo et al., *Genital Human Papillomavirus Infection in Women Who Have Sex With Women*, 178 *J. INFECTIOUS DISEASES* 1604 (1998) (finding that HPV is common among women who have sex with women even if they have not had sex with men).

<sup>95</sup> Eaton et al., *supra* note 93, at 76.

<sup>96</sup> Jennifer Power et al., *Absent Sexual Scripts: Lesbian and Bisexual Women’s Knowledge, Attitudes and Actions Regarding Safer Sex and Sexual Health Information*, 11 *CULTURE, HEALTH & SEXUALITY* 67, 69 (2009) (citing a study conducted in 2000).

<sup>97</sup> Luisa Lina Villa, *Prophylactic HPV Vaccines: Reducing the Burden of HPV-Related Diseases*, 24 *Supplement 1 VACCINE S1/23, S1/23* (2006) (“HPV DNA has been reported in approximately 20% of women who have never had vaginal intercourse, suggesting that abstaining from penetrative intercourse is not completely protective against infection.”).

<sup>98</sup> Jessica P. Brown & J. Kathleen Tracey, *Lesbians and Cancer: An Overlooked Health Disparity*, 19 *CANCER CAUSES & CONTROL* 1009, 1016 (2008).

<sup>99</sup> Jeanne M. Marrazzo, *Genital Human Papillomavirus Infection in Women Who Have Sex with Women: A Concern for Patients and Providers*, 14 *AIDS PATIENT CARE & STDs* 447, 449 (2000).

<sup>100</sup> Carolee Polek & Thomas Hardie, *Lesbian Women and Knowledge about Human Papillomavirus*, 37 *ONCOLOGY NURSING FORUM* E191, E196 (2010).

<sup>101</sup> Marrazzo et al., *supra* note 94, at 1608.

<sup>102</sup> See generally JV Bailey et al., *Sexually Transmitted Infections in Women Who Have Sex With Women*, 80

the vaccine will reach all females. Vaccination campaigns and policies that focus on heterosexual sex and transmission adversely affect WSW and are simply bad health policies.

### 3. Low Income Females

Mandating the vaccination will not only create a sexuality-neutral policy, but also a race-neutral and income-neutral policy. Studies show that low-income populations have higher rates of sexually transmitted infections.<sup>103</sup> Women of color in the United States are more likely to be in this subgroup, many of whom are uninsured and have less access to cervical cancer screenings and regular pap smears.<sup>104</sup> African American females and Hispanic females have a greater likelihood of having cervical cancer<sup>105</sup> and also have a significantly higher risk of death from the disease than Caucasian females.<sup>106</sup> Mandating the vaccination will protect low-income populations and prevent racial minorities from experiencing a negative disparate impact from the burdens of HPV because the vaccine will be more readily accessible.<sup>107</sup> Although it is argued that low-income adolescents can get the vaccine through the Vaccines for Children program, the only way to ensure universal coverage is to mandate the vaccination because this will ensure that all members of the population receive the vaccine.<sup>108</sup>

#### B. Herd Immunity

Vaccines are more effective when given to both sexes, because as more people get vaccinated, the general immunity of the entire population (i.e. the herd) increases.<sup>109</sup> Herd immunity is “the population-level consequence of acquired immunity among some individuals that can reduce the risk of acquiring infection among susceptible individuals.”<sup>110</sup> Herd immunity is the goal of all mass immunization programs and is based on the belief that immunizing a certain portion of the population will create general immunity throughout the population at large.<sup>111</sup> Herd immunity protects persons who have and have not been immunized. Those who

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SEXUALLY TRANSMITTED INFECTIONS 244 (2004) (finding that it is possible for sexually transmitted diseases to occur between women); Katherine Fethers et al., *Sexually Transmitted Infections and Risk Behaviours in Women Who Have Sex With Women*, 76 SEXUALLY TRANSMITTED INFECTIONS 345 (2000) (finding higher STD transmission among women who have sex with women than the control population of the study).

<sup>103</sup> Sara E. Forhan et al., *Prevalence of Sexually Transmitted Infections Among Female Adolescents Aged 14-19 in the United States*, 124 PEDIATRICS 1505, 1510 (2009).

<sup>104</sup> Law, *supra* note 18, at 1764–65.

<sup>105</sup> *Id.* at 1765 (finding Hispanic women have the highest rates of cervical cancer and that African American women are fifty percent more likely to experience cervical cancer than white women).

<sup>106</sup> Globerson, *supra* note 18, at 73.

<sup>107</sup> See Law, *supra* note 18, at 1764 (stating that a disproportionate number of women of color will die unnecessarily if they are not vaccinated at a young age).

<sup>108</sup> Wood, *supra* note 9, at 34.

<sup>109</sup> Palefsky, *supra* note 57, at S16; see also Gregory D. Zimet & Susan L. Rosenthal, *HPV Vaccine and Males: Issues and Challenges*, 117 GYNECOLOGIC ONCOLOGY S26, S29 (2010) (stating that gender-based vaccination policies are less effective and more confusing to the public).

<sup>110</sup> Geoffrey P. Garnett, *Role of Herd Immunity in Determining the Effect of Vaccines against Sexually Transmitted Disease*, 191 J. INFECTIOUS DISEASES S97, S98 (2005).

<sup>111</sup> *Id.* at S98; see also Javitt et al., *supra* note 20, at 388.

are susceptible are protected because high levels of population immunity reduce the likelihood that a susceptible person will come into contact with another susceptible person or someone carrying the disease.<sup>112</sup>

Herd immunity is central to arguments for mandating vaccines in general,<sup>113</sup> and for the HPV vaccine, in particular. The ultimate goal of any vaccination program is the complete eradication of the intended disease. However, policymakers and medical professionals acknowledge that this is an impossible goal,<sup>114</sup> and thus, strategic control of the disease is the focus of vaccination policies. High vaccine coverage is necessary for herd immunity.<sup>115</sup> Although there are varying thresholds for population-level immunity for any given infectious disease, the basic premise behind herd immunity is to vaccinate as many members of the population as possible to create the highest attainable level of general immunity.<sup>116</sup>

Some argue that if all females are vaccinated, then males will be covered by herd immunity as well. However, this argument fails. For cervical cancer prevention, specifically, many researchers and physicians agree that it is important to vaccinate males to prevent the transmission of HPV to females<sup>117</sup> because studies have shown that the transmission of HPV from males to their female partners leads to a significant number of cervical cancer cases.<sup>118</sup>

Studies of other infectious diseases demonstrate that vaccinating only one segment of the population does not decrease disease incidence, and in some cases actually increases transmission overall.<sup>119</sup> Two prime examples are the Rubella and Hepatitis B vaccines. These two vaccination policies failed because both were initially introduced to only a segment of the population and were unsuccessful at reducing the occurrence of the disease. The Rubella vaccine was initially offered to only females, to protect them from the dangers of the disease during pregnancy.<sup>120</sup> However, these female-only policies neither lowered the incidence rates of Rubella nor created generally immunity. It was not until the Rubella vaccine was given to the general population, through state vaccination mandates, that the disease was basically eradicated.<sup>121</sup>

When the FDA approved the Hepatitis B vaccine, it was only offered to certain segments of the population, and consequently, the prevalence of the disease remained high.<sup>122</sup> A reduction

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<sup>112</sup> Garnett, *supra* note 110, at S98.

<sup>113</sup> *Id.* at S98.

<sup>114</sup> Paul Fine et al., "Herd Immunity": A Rough Guide, 52 *CLINICAL INFECTIOUS DISEASES* 911, 914 (2011).

<sup>115</sup> Giuliano, *HPV Vaccination in Males*, *supra* note 67, at S26.

<sup>116</sup> Fine et al., *supra* note 114, at 914–15.

<sup>117</sup> Thomas W. Weiss et al., *Human Papillomavirus Vaccination of Males: Attitudes and Perceptions of Physicians Who Vaccinate Females*, 47 *J. ADOLESCENT HEALTH* 3, 9 (2010).

<sup>118</sup> Giuliano, *HPV Vaccination in Males*, *supra* note 67, at S25 (citing studies that show that cervical cancer in females with one lifetime sexual partner is typically caused by HPV transmission by the male's partner, and that promiscuity in males greatly increases risks of cervical cancer in females).

<sup>119</sup> *Id.* at S25–26.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*; see also Jennifer Caseldine-Bracht, *The HPV Vaccine Controversy: Where are the Women? Where are the Men? Where is the Money?*, 3 *INT'L J. FEMINIST APPROACHES TO BIOETHICS* 99, 104 (2010) ("When the rubella vaccine was introduced in the 1960s, it was originally recommended that only women of child-bearing age get inoculated. However, only when both boys and girls got the vaccine was rubella finally eradicated.").

<sup>122</sup> Sheila M. Rothman & David J. Rothman, *Marketing HPV Vaccine: Implications for Adolescent Health and Medical Professionalism*, 302 *JAMA* 781, 782 (2009).

in Hepatitis B only occurred after states adopted universal vaccination policies.<sup>123</sup> The experiences of the Rubella and Hepatitis B vaccines demonstrate that vaccination policies are neither an effective means of reducing the prevalence of disease nor are they successful at establishing herd immunity when one segment of the population is targeted. Males need to be included in vaccination policies to establish an effective level of herd immunity, which will stop the spread of HPV, and thus reduce the incidences of HPV-related cancer and genital disease.

Some experts have questioned whether it is cost-effective to vaccinate males in addition to females. Gardasil is the most expensive vaccine recommended by the ACIP,<sup>124</sup> and all three doses of the shot cost about \$360 per person.<sup>125</sup> Although many studies suggest that vaccinating males is not cost-effective, these studies only look at cervical cancer prevention and fail to include cancers and infections that affect males.<sup>126</sup> A 2010 study demonstrated that it is cost-effective to include males in vaccination programs when focusing on the benefits to males and females and including all cancers and infections caused by HPV in the analysis.<sup>127</sup> This inclusive study concluded that when the focus is expanded beyond cervical cancer, it is cost-effective to vaccinate both males and females. Moreover, current studies on the cost-effectiveness of the vaccine for both males and females focus solely on heterosexual transmission of the disease between males and females and fail to include the benefits of the vaccine for men who have sex with men (MSM) and women who have sex with women (WSW).<sup>128</sup> These studies also fail to include current research on the increase of HPV-related anal cancer and head and neck cancer.<sup>129</sup> However,

<sup>123</sup> Daniel B. Fishbein et al., *New, and Some Not-so-New, Vaccines for Adolescents and Diseases They Prevent*, 121 PEDIATRICS S5, S10 (2008).

<sup>124</sup> Law, *supra* note 18, at 1748.

<sup>125</sup> Elissa Mendenhall, *Guard Against Gardasil*, 142 MOTHERING MAGAZINE May–June 2007, at 45, 49.

<sup>126</sup> See, e.g., Jane J. Kim & Sue J. Goldie, *Health and Economic Implications of HPV Vaccination in the United States*, 359 NEW ENG. J. MED. 821, 821 (2008) (asserting that it would be cost-effective to vaccinate only females for the benefit of the entire population, assuming there was a high proportion of vaccinated females); see also Harrell W. Chesson et al., *Cost-Effectiveness of Human Papillomavirus Vaccine in the United States*, 14 EMERGING INFECTIOUS DISEASE 244, 247 (2008) (demonstrating that the vaccine is highly cost-effective when focusing only on the benefit to females); Zimet, *Potential Barriers*, *supra* note 55, at 397 (describing the problems with most cost-benefit analysis models that focus solely on cervical cancer).

<sup>127</sup> Elamin H. Elbasha & Erik J. Dasbach, *Impact of Vaccinating Boys and Men Against HPV in the United States*, 28 VACCINE 6858, 6858 (2010). To date, there are no cost-benefit studies of the HPV vaccine for all males, both who have sex with females and who have sex with males. Significantly, a recent study of the incidence of HPV in males, which demonstrated high occurrence of HPV in males, concluded that more information about the prevalence and epidemiology of the infection is necessary for any “realistic cost-effectiveness” study to be conducted. See generally GIULIANO ET AL., *INCIDENCE AND CLEARANCE*, *supra* note 19.

<sup>128</sup> See Harrell Chesson, *HPV Vaccine Cost-Effectiveness: Updates and Reviews*, CTRS. FOR DISEASE CONTROL & PREVENTION, ADVISORY COMM. ON IMMUNIZATION PRACTICES 23 (Feb. 24, 2011), [www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides.../11-4-hpv-cost.pdf](http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides.../11-4-hpv-cost.pdf) (asserting that the study relied on by the ACIP and CDC is limited because it only focuses on heterosexual HPV transmission between females and males). See also Jane J. Kim & Sue J. Goldie, *Cost Effectiveness Analysis of Including Boys in a Human Papillomavirus Vaccination Programme in the United States*, BRIT. MED. J., Oct. 9, 2009, at 7.

A limitation of our analysis is that we only represented heterosexual partnerships and therefore did not reflect HPV transmission among men who have sex with men, who face a high risk of anal cancer and may realise [sic] a greater benefit from HPV vaccination. Such an analysis would require a more comprehensive model that includes a fuller range of sexual behaviours [sic] . . .

<sup>129</sup> Mehanna, *Oropharyngeal Carcinoma*, *supra* note 47, at 880.

separate studies demonstrate that the vaccine is highly cost-effective for the MSM group, especially when focusing on both anal cancer and genital warts.<sup>130</sup>

Current HPV vaccination policies, which target only females, are heteronormative, unfair, and ineffective. Additionally, these policies fail to achieve herd immunity. Universal vaccine administration, through state mandates, will successfully immunize the population and create desired levels of herd immunity because such policies will be inclusive and accessible to all segments of the population.

### III. MANDATING THE HPV VACCINE IS SOUND HEALTH POLICY

Though the medical community has reached a consensus on the necessity of widespread vaccinations, the HPV debate remains a deeply fraught social issue because it is implicated in controversial topics, such as vaccine safety, parental autonomy and adolescent sexuality.<sup>131</sup> In order to mandate the HPV vaccination, states will have to include the vaccine in the list of required vaccinations for school attendance. Studies have proven that school mandates are highly effective at immunizing the population because school-related laws are influential, respected, and followed.<sup>132</sup> Proponents of mandating the HPV vaccination emphasize issues of herd immunity and achieving universal coverage across all sexual orientations and socioeconomic groups.<sup>133</sup> Opponents of an HPV vaccination mandate cite issues of unnecessary promotion and approval of adolescent sexual activity, abrogation of parental autonomy, and the lack of constitutional support because HPV is a sexually transmitted disease, making it different than other vaccines.<sup>134</sup> To see how these arguments have played out in the past, the next section will examine the development of vaccination policies for another disease: Hepatitis B.

#### A. *The Hepatitis B Vaccine as Precedent*

The Hepatitis B vaccine has been cited as precedent for an HPV vaccination mandate.<sup>135</sup>

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<sup>130</sup> Kim, *supra* note 61, at 849.

<sup>131</sup> James Colgrove et al., *HPV Mandates—Lawmaking Amid Political and Scientific Controversy*, 363 *NEW ENG. J. MED.* 785, 785 (2010).

<sup>132</sup> Alan R. Hinman et al., *Childhood Immunizations: Laws that Work*, 20 *J. L. MED. & ETHICS* 122, 122 (2002); *see also* Julie Y. Morita et al., *Effect of a School-Entry Vaccination Requirement on Racial and Ethnic Disparities in Hepatitis B Immunization Coverage Levels Among Public School Students*, 121 *PEDIATRICS* e547, e550–51 (2008) (asserting that school mandated vaccinations for Hepatitis B created more equitable coverage among middle school students of color).

<sup>133</sup> *See* Law, *supra* note 18, at 1764 (arguing that HPV vaccination should be mandated in schools in order to protect the long-term interests of women, low-income people, and racial minorities); *see also* Wood, *supra* note 9, at 34 (stating that a universal HPV vaccine may be the only way to ensure that low-income Hispanic and African American women will have access to the vaccine).

<sup>134</sup> *See* Wood, *supra* note 9, at 34; Colgrove et al., *supra* note 131, at 787 (stating that some social conservatives object to mandatory HPV vaccination policies because they believe the policies undermine abstinence education efforts); Javitt et al., *supra* note 20, at 387–93 (illustrating the view that mandatory HPV vaccinations violate principles of parental autonomy); Law, *supra* note 18, at 1767–71 (stating that courts are unlikely to interfere with parental autonomy with regard to the HPV vaccine because the risk of contracting cancer is statistical and remote); *see also* Susan Levine, *Parents Question HPV Vaccine*, *WASH. POST*, Mar. 4, 2007, at C1 (exploring whether mandatory HPV vaccination policies encourage adolescents to be promiscuous or intrude upon principles of parental autonomy).

<sup>135</sup> *See, e.g.*, Rothman & Rothman, *supra* note 122, at 782–83; Gillian Haber et al., *The HPV Vaccine*

Legal scholars cite it in support of the constitutionality of a HPV mandate,<sup>136</sup> and medical professionals cite it in support of universal coverage.<sup>137</sup> Hepatitis B is similar to HPV in that it is a highly contagious sexually transmitted disease.<sup>138</sup> The experiences of the Hepatitis B vaccine shed light on three specific issues impacting the success of the HPV vaccine: (1) universality; (2) financing; and (3) sexuality.

Similar to the HPV vaccine, the Hepatitis B vaccine was initially targeted at only a segment of the population when it was first approved in the 1980s.<sup>139</sup> However, as discussed in Part II, policymakers soon realized that vaccinating only part of the population did not reduce the prevalence of the disease, and incidence of the disease actually increased between the 1980s and 1990s.<sup>140</sup> It was not until the vaccine was recommended for universal coverage in infants and adolescents by the ACIP in the 1990s that coverage rates began to increase, thus decreasing the prevalence of the disease.<sup>141</sup> Of the Hepatitis B vaccination policies, vaccine expert James Colgrove asserted:

[B]ecause the [Hepatitis B] virus spreads primarily among sexually active people and injection-drug users, some parents argued that the vaccine should be given only to those groups rather than to all children. Such targeting of the vaccine, however, proved to be less effective than universal vaccination in reducing the incidence of the disease.<sup>142</sup>

Funding was a concern for the Hepatitis B vaccine and affected its uptake in the general population. Between the initial introduction of the Hepatitis B vaccine in the 1980s and an upsurge in coverage by the end of the 1990s, the federal government enacted the Vaccines for Children program, mentioned earlier.<sup>143</sup> This program is credited with providing the funding necessary to support universal coverage of the Hepatitis B vaccination.<sup>144</sup>

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*Controversy*, 20 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 325, 326 (2007) (“[W]e have the precedent of school-entry mandates for hepatitis B virus (HBV) vaccine, including ‘catch-up’ requirements in most states for middle school entry. Like HPV, HBV is overwhelmingly a sexually transmitted infection (STI), with few documented cases of casual contact transmission.”).

<sup>136</sup> See, e.g., Kyra R. Wagoner, Comment, *Mandating the Gardasil Vaccine: A Constitutional Analysis*, 5 IND. HEALTH L. REV. 403 (2008); Law, *supra* note 18, at 1757.

<sup>137</sup> See, e.g., Haber et al., *supra* note 135; see also Rothman & Rothman, *supra* note 122.

<sup>138</sup> See *Hepatitis B Facts for Health Care Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#b1> (last visited Apr. 10, 2012); see also Monique H. Lawrence & Mark A. Goldstein, *Hepatitis B Immunization in Adolescents*, 17 J. ADOLESCENT HEALTH 234, 235 (1995) (establishing that one of the risks for children, in addition to risky sexual behavior, was that the disease could be passed through cuts and scrapes, as well as through shared razors and toothbrushes). For an analysis of the Hepatitis B vaccine and use among adolescents see Susan L. Rosenthal et al., *Hepatitis B Vaccine Acceptance Among Adolescents and Their Parents*, 17 J. ADOLESCENT HEALTH 248, 248 (1995).

<sup>139</sup> Rothman & Rothman, *supra* note 122, at 782.

<sup>140</sup> *Id.*; Lawrence & Goldstein, *supra* note 138, at 243–35.

<sup>141</sup> See Rothman & Rothman, *supra* note 122, at 782–83.

<sup>142</sup> James Colgrove, *The Ethics and Policies of a Compulsory HPV Vaccination*, 355 NEW ENG. J. MED. 2389, 2390 (2006).

<sup>143</sup> Rothman & Rothman, *supra* note 122, at 783; Rosenthal et al., *supra* note 138, at 254.

<sup>144</sup> Rothman & Rothman, *supra* note 122, at 783.



Unlike the HPV vaccine, controversy did not surround the Hepatitis B vaccine.<sup>145</sup> Although some parents and providers opposed the universal application of the Hepatitis B vaccination, the opposition was mostly in regards to cost and funding, and less about adolescent sexuality.<sup>146</sup> There is significant public controversy over implementing the HPV vaccination, however, due largely to federal support of abstinence-only education and the rise of the Religious Right in the 1990s and 2000s, which was lacking when the Hepatitis B vaccine was recommended for universal use.<sup>147</sup>

Current federal policies, in addition to the change in political climate, have affected the success of the HPV vaccine, differentiating its experience on the market from the Hepatitis B vaccine. First, the Hepatitis B vaccination was recommended for universal use almost ten years after it was introduced on the market. Contrarily, the HPV vaccine has only been on the market for five years to date. Second, implementing the Hepatitis B vaccine included a struggle for federal funding, which led to the creation of Vaccines for Children. This program already covers the HPV vaccination for both males and females, and so federal funding is not an issue for the HPV vaccine. Cost, nonetheless, is an issue for the HPV vaccine; Gardasil is one of the most expensive vaccines recommended by the ACIP.<sup>148</sup> However, programs like Vaccines for Children allow those who cannot afford the vaccine to get inoculated. Additionally, Merck & Co. offers the vaccine for free to women over age eighteen who do not qualify for the Vaccines for Children program.<sup>149</sup> Third, the political climate has become more protective of adolescent sexuality since the introduction of the Hepatitis B vaccine. The experiences of the Hepatitis B vaccine demonstrate that targeting only a specific segment of the population for vaccination will be unsuccessful in reducing the disease's prevalence, even though the disease is sexually transmitted. Rather than repeating the mistakes of the Hepatitis B vaccine, policymakers should mandate universal coverage now to prevent further increased incidents of genital cancers. The power to lower cancer rates in the United States is in the hands of policymakers. How will they act?

### B. *It is Constitutional to Mandate*

In its seminal decision on mandatory vaccinations, the Supreme Court ruled in *Jacobson*

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<sup>145</sup> Monica J. Casper & Laura M. Carpenter, *Sex, Drugs, and Politics: The HPV Vaccine for Cervical Cancer*, 30 SOCIOLOGY OF HEALTH & ILLNESS 886, 896 (2008) (citing to a conversation the authors had with James Colgrove).

<sup>146</sup> Gary L. Freed et al., *Universal Hepatitis B Immunization of Infants: Reactions from Pediatricians and Family Physicians Over Time*, 93 PEDIATRICS 747, 750–51 (1994); Rosenthal et al., *supra* note 138, at 254 (“Previous studies examining physician attitudes towards hepatitis B immunization has shown that some practitioners have chosen not to implement AAP recommendations because of concerns about the hepatitis B vaccination policy, particularly the financial burden.”).

<sup>147</sup> For a succinct history of the rise of abstinence only education, see Danielle LeClair, Comment, *Let's Talk About Sex Honestly: Why Federal Abstinence-Only-Until-Marriage Education Programs Discriminate Against Girls, are Bad Policy, and Why They Should be Overturned*, 21 WIS. WOMEN'S L. J. 291, 293–99 (2006); see also Kelly Keefe & Amber Oleson, *A New Twist on the Birds and the Bees: Adolescent Female Sexuality and the Debates Surrounding Access to Birth Control, Comprehensive Sex Education, and the HPV Vaccine*, 28 CHILD. LEGAL RTS. J. 13, 20–22 (2008). For a short discussion of the rise of the Religious Right in connection with the HPV vaccine, see Casper & Carpenter, *supra* note 145, at 892–93.

<sup>148</sup> Mendenhall, *supra* note 125, at 49.

<sup>149</sup> *Merck Vaccine Patient Assistance Program*, MERCK, <http://www.merck.com/merckhelps/vaccines/home.html> (last visited Apr. 10, 2012).

*v. Commonwealth of Massachusetts* in 1905 that it is within a state's police power to mandate vaccinations, as long as it is "for the common good, for the protection, safety, prosperity, and happiness of the people."<sup>150</sup> In *Jacobson*, a citizen refused to get the state-mandated smallpox vaccination.<sup>151</sup> The Court held that it was within the power of the Massachusetts legislature to protect the commonwealth from a "disease which threatens the safety of its members."<sup>152</sup> This power is not unlimited, but must serve a "real or substantial relation" to public health and safety.<sup>153</sup> States thus have a constitutional right to mandate a vaccination if a public health necessity exists and the vaccination has a reasonable relationship to that necessity.<sup>154</sup>

States are allowed to mandate vaccinations for children as a condition of school attendance.<sup>155</sup> In 1922, the Supreme Court in *Zucht v. King* upheld a local ordinance requiring vaccinations for school attendance as a valid exercise of state power due to the unique public health concern of a school setting, where children can easily communicate diseases.<sup>156</sup> Currently, state-mandated vaccinations for school attendance are based on ACIP recommendations<sup>157</sup> for certain highly contagious communicable diseases, including influenza, chicken pox, meningococcus, polio, and measles.<sup>158</sup> State-mandated vaccinations have been highly effective in preventing outbreaks of the above-mentioned diseases, and studies show that outbreaks tend to occur in communities where vaccination exemptions are common.<sup>159</sup> In general, school vaccination mandates are viewed positively as an efficient means to vaccinate the population, and are seen as beneficial to society as a whole.

Opponents of a HPV vaccination mandate argue that such a mandate is unconstitutional because HPV is not an airborne disease transmitted in a school setting.<sup>160</sup> These opponents argue that other diseases falling under state mandates for school attendance meet *Jacobson*'s reasonableness requirement because "[a]ll children who attend school are equally at risk of both transmitting and contracting" these highly contagious diseases and as a result "a clear relationship exists between conditioning school attendance on vaccination and the avoidance of the spread of infectious disease within the school environment."<sup>161</sup> Additionally, it has been argued that HPV does not meet the *Jacobson* test because HPV and cervical cancer are not a "widespread epidemic" like smallpox at the time of *Jacobson*.

Nonetheless, the HPV vaccine does meet the *Jacobson* test. A state-mandated HPV

<sup>150</sup> 197 U.S. 11, 27 (internal citations omitted).

<sup>151</sup> *Id.* at 13.

<sup>152</sup> *Id.* at 27.

<sup>153</sup> *Id.* at 31.

<sup>154</sup> Tracey Solomon Dowling, Note, *Mandating a Human Papillomavirus Vaccine: An Investigation into Whether Such Legislation is Constitutional and Prudent*, 34 AM. J.L. & MED. 65, 66 (2008).

<sup>155</sup> James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social and Legal Perspectives*, 90 KY. L.J. 831, 857-58 (2001-2002) ("Despite the mandatory nature of compulsory school vaccination laws, the state's power to require children to be vaccinated as a condition of school entrance has been widely accepted and judicially sanctioned.")

<sup>156</sup> 260 U.S. 174, 177 (1922).

<sup>157</sup> Oleson, *supra* note 72, at 66.

<sup>158</sup> Javitt et al., *supra* note 20, at 389.

<sup>159</sup> Hinman et al., *supra* note 132, at 125.

<sup>160</sup> Javitt et al., *supra* note 20, at 389.

<sup>161</sup> *Id.*

vaccination is constitutional because it serves the rational purpose of working to achieve a health policy goal.<sup>162</sup> HPV is a pressing health issue, and as such, vaccination is a public health necessity: “[P]eople infected with HPV are personally at risk of various diseases and . . . can easily transmit the virus and risk of disease to others.”<sup>163</sup> Additionally, the vaccine has a reasonable relationship to public necessity because it has been proven highly efficacious, and thus, will benefit the population. It is true that HPV is not an “infectious airborne disease,”<sup>164</sup> but it is, nevertheless, highly contagious.<sup>165</sup> Although HPV is not necessarily communicated in a school setting, the Hepatitis B vaccine experience suggests that school-attendance mandates can be applied to sexually transmitted diseases. Mandating the vaccination is the most effective way to immunize the population and reduce the prevalence of HPV-related cancers and infections in the United States. It is therefore constitutional and within a state’s power to mandate the HPV vaccination for school attendance.

### C. *The Benefits Outweigh the Risks*

There were relatively few adverse events connected to the vaccine during clinical drug trials and very few side effects of the vaccine reported since it was first administered in 2006.<sup>166</sup> Most adverse events related to the vaccine in clinical trials involved pain at the injection site or fever.<sup>167</sup> In studies conducted on females, there were very few serious adverse events. In one study of 2,673 female participants, there was one serious adverse incident,<sup>168</sup> and in a second study of 6,019 female participants there were seven serious adverse incidents.<sup>169</sup> In this second study, conducted by Members of the Females United to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) II Study Group, the participants were followed for up to three years after administration of the vaccine, and within this extended period there was only a .01% risk of any serious adverse incident.<sup>170</sup> There were fewer adverse incidents connected to the vaccine reported in studies of males in comparison to studies of females, which researchers attribute to the higher levels of muscle mass in males at injection sites.<sup>171</sup> For the male-only studies, most adverse events reported in trials were not serious and, similar to the female-only trials, related to pain at the injection site or fever.<sup>172</sup> In one study of male participants, there were no serious adverse

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<sup>162</sup> Law, *supra* note 18, at 1753–54 (arguing that HPV as a highly contagious disease and as such meets the principles set forth in *Jacobson*).

<sup>163</sup> *Id.* at 1753.

<sup>164</sup> Lawrence O. Gostin & Catherine D. DeAngelis, *Mandatory HPV Vaccine: Public Health vs. Private Wealth*, 297 JAMA 1921, 1922 (2007).

<sup>165</sup> Law, *supra* note 18, at 1754.

<sup>166</sup> Zimet, *Potential Barriers*, *supra* note 55, at 391.

<sup>167</sup> See Barbara A. Slade et al., *Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine*, 302 JAMA 750 (2009) (describing physical reactions to the vaccine injection); see generally Garland et al., *supra* note 63 (providing an analysis of an HPV vaccine trial); The FUTURE II Study Group, *Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions*, 356 NEW ENG. J. MED. 1915 (2007) [hereinafter The FUTURE II Study Group] (providing procedural information of an HPV vaccine trial).

<sup>168</sup> Garland et al., *supra* note 63, at 1934–35, 1940.

<sup>169</sup> The FUTURE II Study Group, *supra* note 167, at 1924.

<sup>170</sup> *Id.*

<sup>171</sup> Giuliano et al., *HPV in Males*, *supra* note 67, at 409.

<sup>172</sup> *Id.*

events reported.<sup>173</sup>

After a vaccine goes to market, all adverse incidents are reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is co-sponsored by the FDA and the CDC and monitors vaccines after they have been administered to the population.<sup>174</sup> VAERS monitors vaccines by receiving reports about adverse events from providers, manufacturers, and individuals.<sup>175</sup> VAERS is described as “a national, voluntary, passive surveillance system.”<sup>176</sup> A recent study on VAERS reports about the HPV vaccine demonstrated that significant adverse events are not associated with the vaccine.<sup>177</sup> Researchers stated: “Our review of 12,424 reports of [reported adverse events] following receipt of [the] HPV [vaccine] after licensure found that most did not meet the FDA definition of serious.”<sup>178</sup> The vaccine will continue to be monitored by VAERS, but current studies do show that the vaccine is safe.

Researchers still do not know how long the effectiveness of the vaccine will last, and if those vaccinated will need a booster shot at some point. Studies comparing the epidemiology of the vaccine to that of the Hepatitis B vaccine have been conducted in order to examine the potential long-term effectiveness of the vaccine.<sup>179</sup> Studies of the Hepatitis B vaccine reveal that the long-term immunity of the vaccine is connected to its ability to induce immune memory in the body.<sup>180</sup> Clinical trials of the HPV vaccine demonstrate that the drug is effective in inducing immune memory for at least up to five years,<sup>181</sup> and that the development of the immune memory is similar to that of Hepatitis B.

The fact that the long-term effectiveness of the vaccine is unknown is not a reason to discount the benefits and relatively low risks of the vaccine. There are many vaccines currently administered that require subsequent booster shots.<sup>182</sup> In a 2007 article on the risk and benefits of HPV, *New York Times* Medical Health Specialist Jane E. Brody asserted in response to an inquiry about the long-term safety and efficacy of the vaccine: “[W]e do have at least five years of safety data that include no hints of long-term risks or waning effectiveness. But if the vaccine should begin to lose potency over time, that could easily be remedied by a booster shot.”<sup>183</sup> Current data shows that the vaccine is highly effective and the risks of adverse events are very low. Thus, the

<sup>173</sup> *Id.*

<sup>174</sup> VACCINE ADVERSE EVENT REPORTING SYSTEM, <http://vaers.hhs.gov/index> (last visited Apr. 10, 2012).

<sup>175</sup> *About the VAERS Program*, VACCINE ADVERSE EVENT REPORTING SYSTEM, <http://vaers.hhs.gov/about/index> (last visited Apr. 10, 2012).

<sup>176</sup> *See generally* Slade et al., *supra* note 167 (describing minimal adverse physical reactions post-vaccination).

<sup>177</sup> *Id.* at 755.

<sup>178</sup> *Id.*

<sup>179</sup> *See, e.g.*, Kevin A. Ault, *Long-Term Efficacy of the Human Papillomavirus Vaccination*, 107 GYNECOLOGIC ONCOLOGY S27, S29 (2007) (comparing Hepatitis B and HPV vaccine studies and finding that long-term vaccine efficiency is dependent on a “robust immune memory”).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at S29–30.

<sup>182</sup> *See Tetanus (Lockjaw) Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm> (last visited Apr. 10, 2012) (discussing the need for a tetanus booster every ten years); *Pertussis (Whooping Cough) Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/pertussis/default.htm> (last visited Apr. 10, 2012) (discussing the booster shot for Pertussis, Tetanus, and Diphtheria).

<sup>183</sup> Jane E. Brody, *HPV Vaccine: Few Risks, Many Benefits*, N.Y. TIMES, May 15, 2007, at F7.

benefits of the HPV vaccine clearly outweigh the risks, and the potential for vaccine risks, or even a reduction in immunity, should not weigh against mandating the vaccine for school attendance.

#### D. Good Health Policy

Mandating the HPV vaccine is sound health policy. A universal mandate will allow for timely coverage, broader education and higher levels of awareness, and prevent stigmatization of MSM and the exclusion of WSW. Additionally, a universal vaccine will create higher levels of immunity throughout the population.

Education is key to the success of the HPV vaccine. Studies demonstrate that once awareness of HPV is increased, there is typically a desire to obtain the HPV vaccine.<sup>184</sup> However, males are significantly less knowledgeable about HPV and the health consequences of HPV than females.<sup>185</sup> Specifically, studies show that there is limited knowledge of HPV among MSM.<sup>186</sup> In one study of gay and bisexual males, although very well aware that HPV was an STI, the participants often did not know that HPV could lead to genital warts, and even fewer knew that HPV could cause anal and penile cancer.<sup>187</sup> Although the dearth of knowledge among males in general can be partly attributed to the focus of Merck & Co.'s advertising campaign on females and parents of females,<sup>188</sup> the lack of knowledge among males, regardless of sexuality, is alarming. Scholars indicate that without mandating the vaccination, it will be hard to encourage males to get vaccinated at a young age because the parents of males have been unengaged in conversations around HPV and the vaccine.<sup>189</sup>

Abstinence-only education across the United States prevents an increase in STI education. Although conservatives argue that mandating the HPV vaccination will undermine efforts made by abstinence-only education and cause more adolescents to engage in sexual activities,<sup>190</sup> this argument is built on a faulty foundation because countless studies have proven that abstinence-only education does not prevent adolescents from engaging in sexual activities.<sup>191</sup> In fact, abstinence-only education neither delays “the age of sexual initiation, nor . . . decrease[s] the number of sexual encounters” adolescents have.<sup>192</sup> It is argued that abstinence-only education is actually dangerous for adolescents because it “leav[es] them perilously unaware, or even misinformed about genuine probable risks” of sex by not teaching about STIs or contraception.<sup>193</sup>

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<sup>184</sup> Monica Christine R. Nandwani, *Men's Knowledge of the Human Papillomavirus Vaccine*, 35 NURSE PRACTITIONER 32, 38 (2010) (discussing a correlation between HPV awareness and an increased vaccination intent in men); see also Reiter et al., *supra* note 81, at 199 (observing that approximately 74% of male study participants were willing to get the HPV vaccine).

<sup>185</sup> Zimet & Rosenthal, *supra* note 109, at S26; Nandwani, *supra* note 184, at 36.

<sup>186</sup> Reiter et al., *supra* note 81, at 200.

<sup>187</sup> *Id.* at 199.

<sup>188</sup> Nandwani, *supra* note 184, at 37.

<sup>189</sup> Liddon et al., *supra* note 75, at 2.

<sup>190</sup> Wood, *supra* note 9, at 34; Colgrove et al., *supra* note 131, at 787.

<sup>191</sup> Bleakley et al., *supra* note 10, at 1152.

<sup>192</sup> R. Alta Charo, *Politics, Parents, and Prophylaxis—Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905, 1907 (2007); see also Michelle Fine & Sara I. McClelland, *Sexuality Education and Desire: Still Missing After all These Years*, 76 HARV. EDUC. REV. 297, 312 (2006) (discussing findings that abstinence-only programs do not delay intercourse).

<sup>193</sup> Globerson, *supra* note 18, at 89.

If knowledge is key to HPV administration and uptake in the population, then these programs create a concrete barrier to the reduction of HPV by failing to educate adolescents about STIs.

STIs in general, and HPV in particular, are highly prevalent among adolescents and young adults.<sup>194</sup> Studies demonstrate that HPV infection occurs at a higher rate right after an individual's sexual debut.<sup>195</sup> Studies show that by age fourteen or fifteen, a significant percentage of adolescents have engaged in sexual activities and about twenty-five percent of adolescents have engaged in vaginal sex.<sup>196</sup> It is argued that in states with high levels of abstinence-only education, adolescents are less likely to engage in vaginal or anal sex but are choosing oral sex at higher rates.<sup>197</sup> Due to the rigidity of the abstinence-only education they are receiving, these teens are unaware of the STI risks associated with oral sex, and are unknowingly increasing their risk levels for HPV and other STIs that can be transmitted through oral sex.<sup>198</sup> One study stated, "HPV DNA has been reported in approximately 20% of women who have never had vaginal intercourse, suggesting that abstaining from penetrative intercourse is not completely protective against infection."<sup>199</sup> Abstinence-only education fails to educate adolescents about STI risks from sexual activity, and thus adolescents remain highly susceptible to HPV transmission. Researchers argue that only comprehensive sexual education, which speaks to the risks of STIs and teaches adolescents about contraception and safe sex, will reduce the high prevalence of sexually transmitted diseases among adolescents.<sup>200</sup>

Opponents of the HPV vaccination argue that vaccinating adolescents for a sexually transmitted disease will give them a false sense of security and increase sexual activities.<sup>201</sup> However, this argument has never been proven to be correct. A sociologist from the CDC was cited in the *New England Journal of Medicine* for the proposition that "fear of sexually transmitted diseases has not been a major motivation for adolescents to abstain from sex [] and the availability of condoms and emergency contraception has not had measurable effects on the frequency of unsafe behavior."<sup>202</sup> Comparisons to condom availability are made to refute the argument that the HPV vaccination will increase adolescent sexual activities.<sup>203</sup> The availability of condoms in schools did not change the number of adolescents having sex, but rather, according to CDC studies, made adolescent sex safer by increasing condom usage.<sup>204</sup> Additionally, studies

<sup>194</sup> See, e.g., Susan L. Rosenthal & Lawrence R. Stanberry, *Parental Acceptability of Vaccines for Sexually Transmitted Infections*, 159 ARCHIVES OF PEDIATRIC & ADOLESCENT MED. 190, 190 (2005) ("About half of the 18 million new STI cases in 2000 were among those between 15 and 25 years of age.").

<sup>195</sup> Forhan et al., *supra* note 103, at 1509–10.

<sup>196</sup> Gregory D. Zimet, *Improving Adolescent Health: Focus on HPV Vaccine Acceptance*, 37 J. ADOLESCENT HEALTH S17, S17 (2005); Bleakley et al., *supra* note 10, at 1151.

<sup>197</sup> Globerson, *supra* note 18, at 91.

<sup>198</sup> *Id.*

<sup>199</sup> Villa, *supra* note 97, at S1/23 (citing Catherine Ley et al., *Determinants of Genital Human Papillomavirus Infection in Young Women*, 83 J. NAT'L CANCER INST. 997, 1003 (1991)).

<sup>200</sup> Forhan et al., *supra* note 103, at 1510.

<sup>201</sup> See generally Gibbs, *supra* note 9 (explaining that some opponents of the vaccination believe it will be detrimental to the sexual activities of teenagers); see also Globerson, *supra* note 18, at 89; Wood, *supra* note 9, at 34.

<sup>202</sup> Robert Steinbrook, *The Potential of Human Papillomavirus Vaccines*, 354 NEW ENG. J. MED. 1109, 1112 (2006) (citing the opinion of Nicole Liddon, a CDC sociologist).

<sup>203</sup> Monk & Wiley, *supra* note 10, at 421.

<sup>204</sup> See *id.* (asserting that the HPV vaccine will not negatively affect teenage sexual relations since the availability of condoms has not).

have shown that access to emergency contraception has not increased adolescent sex or spurred younger adolescents to engage in sex.<sup>205</sup> A 2006 article in the *Journal of Obstetrics and Gynecology* stated the point perfectly: “Seat belts do not cause reckless driving, tetanus shots do not cause children to seek out rusty nails, and the [H]epatitis B vaccination has not altered sexual practices.”<sup>206</sup>

An additional argument against mandating the vaccination is that making it a requirement for school attendance undercuts parental autonomy because mandatory vaccinations necessarily impinge on a parent’s decision to vaccinate his or her child. The Supreme Court has stated repeatedly that parents have the fundamental right to control their child’s upbringing.<sup>207</sup> It has been argued that a parent’s fundamental right to direct a child’s upbringing extends to issues of birth control, sex, and the HPV vaccination.<sup>208</sup> However, parental autonomy with respect to one’s children is not limitless.<sup>209</sup> Parental decisions based on religious beliefs or moral values are not allowed to subject children to harm.<sup>210</sup> In 1944, the Supreme Court stated in *Prince v. Massachusetts* that “[p]arents may be free to become martyrs themselves. But it does not follow that they are free, in identical circumstances, to make martyrs of their children . . . .”<sup>211</sup> Parental autonomy can be limited by a mandated HPV vaccination, as it is with other school-mandated vaccinations. HPV vaccine proponents should focus on the universal acquisition of the disease and its serious negative health consequences in order to encourage parental acceptance of the vaccine.

Some argue that legislation with wide parental exemptions is the only appropriate way to enact HPV vaccination legislation.<sup>212</sup> Although not constitutionally required to do so, states can allow exemptions to vaccination mandates,<sup>213</sup> and states can choose not to allow exemptions.<sup>214</sup> All states must have medical exemptions,<sup>215</sup> most have religious exemptions,<sup>216</sup> and a small number allow for philosophical exemptions.<sup>217</sup> However, in *Prince v. Massachusetts*, the Supreme Court asserted that religious rights can be preempted when societal values and welfare are threatened: “Thus, [a parent] cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or

<sup>205</sup> See *id.* (citing a 2005 study on the effects of emergency contraception on sexual practices).

<sup>206</sup> *Id.* at 421.

<sup>207</sup> See *supra* note 5.

<sup>208</sup> Keefe & Oleson, *supra* note 147, at 14.

<sup>209</sup> *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944).

<sup>210</sup> See *id.* (arguing that the state may infringe upon a guardian’s decision pertaining to her child if it harms the child).

<sup>211</sup> *Id.* at 169.

<sup>212</sup> See Law, *supra* note 18, at 1768; see also Wood, *supra* note 9, at 34.

<sup>213</sup> Law, *supra* note 18, at 1768.

<sup>214</sup> See *Workman v. Mingo Cnty. Sch.*, 667 F. Supp. 2d 679, 689 (S.D. W. Va. 2009) (citing case law from other states and district courts that do not allow exemptions for vaccines).

<sup>215</sup> Law, *supra* note 18, at 1765.

<sup>216</sup> See Anthony Ciolli, *Religious & Philosophical Exemptions to Mandatory School Vaccinations: Who Should Bear the Costs to Society*, 74 MO. L. REV. 287, 287 (2009) (asserting that West Virginia and Mississippi are the only two states that do not allow religious exemptions for mandatory vaccinations).

<sup>217</sup> Dowling, *supra* note 154, at 70.

death.”<sup>218</sup>

There are two main arguments against allowing exemptions for an HPV vaccination mandate. First, allowing exemptions prevents successful herd immunity.<sup>219</sup> Unvaccinated children and adolescents are a potential threat to the general population, and specifically, if they are clustered together, are a threat to themselves because there is clear evidence that with less stringent vaccination requirements, there are more outbreaks of “vaccine preventable infections.”<sup>220</sup> Second, parental decisions and adolescents’ sexual choices are not necessarily in sync. A parent’s decision to not vaccinate his or her child might put that adolescent at risk, because regardless of what a parent believes, it is the adolescent’s decision whether or not to have sex.<sup>221</sup> According to a recent article in *Pediatrics*, “Because a substantial proportion of female adolescents acquire HPV infection soon after sexual initiation and parents typically fail to predict the timing of their daughters’ sexual initiation, routine vaccination of preadolescent girls . . . is of critical importance.”<sup>222</sup> Mandating the HPV vaccination will protect all males and females from dangerous health burdens, not for the sake of their parents, or based on their parents’ religious beliefs,<sup>223</sup> but for their own sake. Thus, not only is it constitutional to mandate the HPV vaccination for school attendance, but it is also sound health policy to do so.

#### IV. CONCLUSION

As of July 2011, only Virginia and Washington D.C. had passed legislation mandating the vaccination for school attendance.<sup>224</sup> Both laws have widely applicable opt-out provisions, which make it easy for parents to choose not to vaccinate their adolescents.<sup>225</sup> In 2007, there were twenty states considering similar legislation, none of which were passed.<sup>226</sup> The failure of these laws is attributed to the power of moral conservatives and the Religious Right.<sup>227</sup> However, the tide is shifting. There were significantly more bills proposed in state legislatures between 2009 and 2010 than in previous years. In the past two years, states have increasingly enacted

<sup>218</sup> *Prince*, 321 U.S. at 166–68.

<sup>219</sup> Wagoner, *supra* note 136, at 435.

<sup>220</sup> Zimet, *Potential Barriers*, *supra* note 55, at 392; *see also* Wagoner, *supra* note 136, at 435–36.

<sup>221</sup> Renee Gerber, *Mandatory Cervical Cancer Vaccinations*, 35 J.L. MED. & ETHICS 495, 496 (2007).

<sup>222</sup> Forhan et al., *supra* note 103, at 1510.

<sup>223</sup> Gerber, *supra* note 221, at 495.

<sup>224</sup> D.C. CODE § 7-1651.04 (b)(1)(B)(iii) (2008); VA. CODE ANN. § 32.1-46 (D)(3) (2008); *see also* HPV Vaccine, NATIONAL CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/default.aspx?tabid=14381> (last visited Apr. 10, 2012).

<sup>225</sup> VA. CODE ANN. § 32.1-46 (D)(3) (2008).

Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent’s or guardian’s sole discretion, may elect for the parent’s or guardian’s child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.

*Id.* D.C. CODE § 7-1651.04(b)(1)(B)(i) (2008) (“The parent or legal guardian [can object] in good faith [if] . . . the vaccination would violate his or her religious beliefs.”); D.C. CODE § 7-1651.04(b)(1)(B)(iii) (2008) (“The parent or legal guardian, in his or her discretion, [can elect] to opt out of the HPV vaccination program, for any reason.”).

<sup>226</sup> Casper & Carpenter, *supra* note 145, at 894.

<sup>227</sup> *Id.* at 892.



legislation mandating insurance coverage for the vaccine, funding the vaccine for uninsured or underinsured adolescents, or requiring education on the dangers of HPV. This increase in legislative activity signals a recognition by policymakers of the importance of the HPV vaccine.<sup>228</sup> However, there is more work to be done. In addition to legislative efforts, more cost-effectiveness analyses need to be completed to demonstrate that it is cost-effective to vaccinate the entire population. More studies need to be completed on the long-term efficacy of the vaccine. And education initiatives are necessary to educate the population on the dangers of HPV and the benefits of the vaccine.

A 2010 study from Australia demonstrated high efficacy of the vaccine in reducing rates of genital warts.<sup>229</sup> In April 2007, the Australian government started a program aimed at vaccinating all girls at age twelve.<sup>230</sup> The program also included a catch-up vaccination for all females over the age of twelve.<sup>231</sup> Researchers stated that prior to the introduction of the vaccination, rates of genital warts stayed relatively stable; however, after the government-initiated program, rates of genital warts among females dropped significantly.<sup>232</sup> The study highlighted the high efficacy of the vaccine. This Australian study is the first non-clinical study of a comprehensive vaccination program, and demonstrated promising results for such a program in the United States.<sup>233</sup>

In the United States, there are larger societal issues implicated by the HPV vaccine controversy. Abstinence-only education is not working and is putting adolescents at risk. Comprehensive sexual education is necessary; federal dollars should be spent on educating teens about safe sex and contraception. Discourses on the sexual health of men who have sex with men, and women who have sex with women need to be included in sexual education classes as well. The heterosexual focus of medical conversations needs to be redirected, and health policies, particularly sexual health policies, need to focus on all members of the population. The HPV vaccine will benefit the public, and will reduce the prevalence of certain cancers in the United States. Mandating the vaccine will efficiently and effectively immunize the population and be beneficial to public health. In the case of HPV, inclusion is key, so that all members of society are included, and no group is left out.

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<sup>228</sup> See *HPV Vaccine*, NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 224 (explaining that twenty states have enacted legislation regarding the HPV vaccine).

<sup>229</sup> Basil Donovan et al., *Quadrivalent Human Papillomavirus Vaccination and Trends in Genital Warts in Australia: Analysis of National Sentinel Surveillance Data*, 11 *LANCET INFECTIOUS DISEASES* 39, 39 (2011).

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *Id.* at 41–42.

<sup>233</sup> *Id.* at 43. Significantly, the study found that the government sponsored vaccination program, which only targeted females, had no impact on the occurrence rates of genital warts among men who have sex with men. *Id.*