

## The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?

Carrie A. Roll

Follow this and additional works at: <http://digitalcommons.law.umaryland.edu/jhclp>



Part of the [Health Law Commons](#), and the [Public Health Commons](#)

---

### Recommended Citation

Carrie A. Roll, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*, 10 J. Health Care L. & Pol'y 421 (2007).  
Available at: <http://digitalcommons.law.umaryland.edu/jhclp/vol10/iss2/9>

This Notes & Comments is brought to you for free and open access by DigitalCommons@UM Carey Law. It has been accepted for inclusion in Journal of Health Care Law and Policy by an authorized administrator of DigitalCommons@UM Carey Law. For more information, please contact [smccarty@law.umaryland.edu](mailto:smccarty@law.umaryland.edu).

# THE HUMAN PAPILLOMAVIRUS VACCINE: SHOULD IT BE MANDATORY OR VOLUNTARY?

CARRIE A. ROLL\*

## INTRODUCTION

In September 2006, Michigan proposed the first legislation of its kind, mandating vaccination of all girls with Gardasil, the new human papillomavirus (HPV) vaccine, before they could enter the sixth grade.<sup>1</sup> Although the bill passed by an overwhelming majority in the Michigan Senate, it was narrowly defeated in the State House of Representatives.<sup>2</sup> Following Michigan's lead, many other states have proposed similar legislation that would mandate HPV vaccination for all pre-adolescent girls as a condition for school entry.<sup>3</sup> In Texas, the governor bypassed the state legislature altogether and issued an executive order requiring HPV vaccination.<sup>4</sup>

These state actions have triggered a debate between vaccine advocates, who believe the HPV vaccine should be widely administered to prevent cervical cancer, and social conservatives who fear that vaccinating pre-adolescents and adolescents will encourage premarital sex.<sup>5</sup> Furthermore, because the HPV vaccine protects against a disease that is transmitted primarily through sexual contact,<sup>6</sup> mandatory vaccination for school entry raises legal issues not present with regard to

---

Copyright © 2007 by Carrie A. Roll.

\* J.D. and M.P.H. Candidate, 2008, University of Maryland School of Law (Baltimore, MD). B.S., Colorado State University (Fort Collins, CO). I would like to thank the editorial staff of the *Journal* for preparing this article for publication. I would also like to thank my husband for his support and encouragement through many years of school.

1. S. 1417, 2006 Leg., 93rd Sess. (Mich. 2006).

2. Tim Martin, *Vaccine Backers Again Target Capitol*, S. BEND TRIB., Jan. 30, 2007, available at <http://www.southbendtribune.com/apps/pbcs.dll/article?AID=/20070130/News01/701300391>.

3. See *infra* Part III.A.

4. Ralph Blumenthal, *Texas Is First to Require Cancer Shots for Schoolgirls*, N.Y. TIMES, Feb. 3, 2007, at A9.

5. Rob Stein, *Cervical Cancer Vaccine Gets Injected with a Social Issue*, WASH. POST, Oct. 31, 2005, at A3.

6. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., GENITAL HPV INFECTION FACT SHEET 1 (2004), <http://www.cdc.gov/std/HPV/hpv.pdf> [hereinafter CDC FACT SHEET].

mandatory vaccinations against diseases transmitted through the air or through casual contact.<sup>7</sup>

Because of the legal and social implications of requiring HPV vaccination for school entry, the best course of action is to administer the vaccine on a voluntary basis with the express permission of the parents. HPV is primarily transmitted by sexual contact, which implicates lifestyle choices and behavioral decisions.<sup>8</sup> Mandatory school vaccination laws make sense when the disease is easily spread, either through the air or by casual contact.<sup>9</sup> However, mandatory vaccination for a sexually transmitted infection is not a reasonable approach.<sup>10</sup> Therefore, states should not mandate HPV vaccination as a condition for school entry at this time. Rather, states should focus on educating parents regarding the link between cervical cancer and HPV, with the goal of encouraging voluntary HPV vaccination.

This article will examine the legal and social implications of requiring HPV vaccination for girls as a condition of school entry. Part I will discuss the importance and effectiveness of the HPV vaccine in the prevention of cervical cancer and describe the debate regarding mandatory vaccination. Part II will analyze whether mandatory HPV vaccination as a condition for school entry is analogous to other mandatory infectious disease vaccination laws or to laws requiring human immunodeficiency virus (HIV) testing for at-risk individuals. Part II will also discuss informed consent issues surrounding mandatory HPV vaccination. Finally, Part III of this article will discuss the proposed mandatory HPV vaccination legislation and analyze this legislation from the opposing perspectives of public health advocates and social conservatives. In addition, Part III will offer a recommendation for the best way to implement HPV vaccination programs in light of these opposing perspectives.

## I. BACKGROUND

### A. *The Need for the HPV Vaccine*

HPV is the most common sexually transmitted infection in the United States.<sup>11</sup> Approximately twenty million men and women in the United States are currently infected with genital HPV, and approximately 6.2 million individuals will acquire a new genital HPV infection each year.<sup>12</sup> The incidence of HPV is highest

---

7. Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 VACCINE 4812, 4815 (2006).

8. *Id.*

9. *Id.*

10. *Id.*

11. Hillard Weinstock et al., *Sexually Transmitted Diseases Among American Youth: Incidence and Prevalence Estimates, 2000*, 36 PERSP. SEXUAL & REPROD. HEALTH 6, 9 (2004).

12. CDC FACT SHEET, *supra* note 6.

among sexually active adolescent girls and young adult women aged fifteen to nineteen.<sup>13</sup> In addition, by age fifty at least eighty percent of women will have acquired an HPV infection.<sup>14</sup>

HPV can be transmitted through genital contact and, because most HPV infections are asymptomatic, infected individuals may be unaware of their status and thereby unknowingly infect their sexual partners.<sup>15</sup> Furthermore, condoms may not be effective in preventing HPV transmission because the virus may be present on the skin beyond the area covered by the condom.<sup>16</sup> Once contracted, there is no cure for HPV.<sup>17</sup>

There are over 100 strains or types of HPV, of which more than thirty are sexually transmitted and can infect the genital tract.<sup>18</sup> Approximately ten of the thirty identified sexually transmissible HPV types can lead to the development of cervical cancer and are accordingly classified as high-risk types.<sup>19</sup> Persistent infection with one or more high-risk HPV types is the main risk factor for cervical cancer.<sup>20</sup> HPV Types 16 and 18 are considered high-risk because of their association with seventy percent of cervical cancer cases.<sup>21</sup> There are also low-risk HPV types, such as Types 6 and 11, which are not associated with cervical cancer but are associated with ninety percent of genital warts cases.<sup>22</sup>

In 2007, an estimated 11,150 cases of invasive cervical cancer are expected to be diagnosed and cervical cancer is expected to cause approximately 3,670 deaths in the United States alone.<sup>23</sup> The fact that cervical cancer deaths in this country were limited to less than 3,700 in 2005 reflects the success of cytological screening by the Papanicolaou (Pap) test.<sup>24</sup> The Pap test detects abnormalities in the cells of a

---

13. John W. Sellors et al., *Incidence, Clearance and Predictors of Human Papillomavirus Infection in Women*, 168 CAN. MED. ASS'N J. 421, 424 (2003).

14. CDC FACT SHEET, *supra* note 6.

15. *Id.*

16. David Soper, *Clinical Study: Reducing the Health Burden of HPV Infection Through Vaccination*, 2006 INFECTIOUS DISEASES OBSTETRICS & GYNECOLOGY 1, 1 (2006).

17. CDC FACT SHEET, *supra* note 6.

18. *Id.*

19. *Id.*

20. *Id.*

21. Luisa L. Villa et al., *Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, and 18) L1 Virus-Like Particle Vaccine in Young Women: A Randomised Double-Blind Placebo-Controlled Multicentre Phase II Efficacy Trial*, 6 LANCET ONCOLOGY 271, 271 (2005).

22. *Id.*

23. AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2007, at 20 (2007), available at <http://www.cancer.org/downloads/STT/CAFF2007PWSecured.pdf>. Worldwide, cervical cancer has an even more significant impact, with an estimated 500,000 new cases and 250,000 deaths per year. OFFICE OF WOMEN'S HEALTH, NAT'L CANCER INST., CERVICAL CANCER OVERVIEW, <http://women.cancer.gov/research/cervical.shtml>.

24. Richard Roden & T.-C. Wu, *How Will HPV Vaccines Affect Cervical Cancer?*, 6 NATURE REV. CANCER 753, 753 (2006).

woman's cervix that are indicative of cervical cancer.<sup>25</sup> Although the Pap test has been a highly successful tool in screening for the early identification of cervical cancer, there is a significant financial burden in treating pre-cancerous lesions and in performing further testing to eliminate false positives that arise in Pap tests.<sup>26</sup> As such, vaccination may be the most cost-effective approach to combat HPV and cervical cancer, given that vaccination has traditionally been the best approach to combat other infectious diseases.<sup>27</sup>

### B. *The Effectiveness of the HPV Vaccine*

Gardasil is the first vaccine developed to prevent cervical cancer caused by HPV Types 16 and 18 and genital warts caused by HPV Types 6 and 11.<sup>28</sup> Its effectiveness has been studied in several international trials involving 21,000 women aged sixteen to twenty-six.<sup>29</sup> In two randomized, placebo-controlled trials, Gardasil reduced the incidence of persistent HPV infection and pre-cancerous lesions by ninety to 100 percent among women aged sixteen to twenty-three years.<sup>30</sup> Additionally, the vaccine was proven to be highly immunogenic.<sup>31</sup> All women given the active vaccine developed higher detectable antibody responses to HPV than did women with natural antibody titers due to prior HPV infection who were given a placebo.<sup>32</sup>

---

25. NAT'L CANCER INST., THE PAP TEST: QUESTIONS AND ANSWERS 1 (2006), available at [http://www.cancer.gov/images/Documents/6e8424db-12f5-4b8a-b160-e8d010fd6026/Fs5\\_16.pdf](http://www.cancer.gov/images/Documents/6e8424db-12f5-4b8a-b160-e8d010fd6026/Fs5_16.pdf).

26. Matthew F. Daley et al., *A National Survey of Pediatrician Knowledge and Attitudes Regarding Human Papillomavirus Vaccination*, 118 PEDIATRICS 2280, 2281 (2006). Cervical cancer screening programs reduced the incidence of cervical cancer by approximately eighty percent, but cost the United States more than six billion dollars in 2005. Roden & Wu, *supra* note 24, at 753.

27. Roden & Wu, *supra* note 24, at 753.

28. Press Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health (June 8, 2006), <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html> [hereinafter FDA Press Release]. A competing bivalent HPV vaccine that protects against HPV Types 16 and 18 is being developed by GlaxoSmithKline (GSK). GlaxoSmithKline, Challenging Cancer, <http://www.gsk.com/infocus/cancer-treatments.htm> (last visited August 16, 2007). GSK has applied for approval of its vaccine in the United States, Europe, and its International Region. GLAXOSMITHKLINE, ACCESS TO MEDICINES: GSK CORPORATE RESPONSIBILITY REPORT 2005, at 17 (2005).

29. FDA Press Release, *supra* note 28.

30. Villa et al., *supra* note 21, at 272, 277; see also Finn Egil Skjeldestad, *Prophylactic Quadrivalent Human Papillomavirus (HPV) (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine (Gardasil™) Reduces Cervical Intraepithelial Neoplasia (CIN) 2/3 Risk*, 43rd Annual Meeting of the Infectious Disease Soc'y of Am., Abstract LB-8a (Oct. 6-9, 2005), at 53, available at <http://www.idsociety.org/Template.cfm?Section=Home&CONTENTID=14108&TEMPLATE=/ContentManagement/ContentDisplay.cfm>. The vaccine was 100 percent effective when subjects received three doses and ninety-seven percent effective when subjects received only one or two doses. *Id.*

31. Villa et al., *supra* note 21, at 277.

32. *Id.*

Studies were also conducted to measure the immune response to the vaccine among younger females aged nine to fifteen years.<sup>33</sup> In one study, researchers compared the immune response to the vaccine between boys and girls ages ten to fifteen and young women ages sixteen to twenty-three.<sup>34</sup> The neutralizing antibody response was 1.7 to 2.7 times higher in the group of ten- to fifteen-year-old boys and girls than the response observed in the group of sixteen- to twenty-three-year-old young women.<sup>35</sup> These studies also indicate that the vaccine is only effective when it is given prior to HPV infection.<sup>36</sup> These results suggest that HPV vaccination will be most effective for ten- to thirteen-year-olds, who are most likely HPV negative.<sup>37</sup>

All of these studies showed that Gardasil was generally well tolerated in the study populations, with no serious adverse side effects.<sup>38</sup> The most commonly reported adverse effects were headaches, fever, pain, and swelling and redness at the injection site.<sup>39</sup> Interestingly, the proportion of study participants who reported at least one adverse effect was lower among the group of boys and girls than among the group of sixteen- to twenty-three-year-old females.<sup>40</sup> As with other vaccines, however, it is always possible that unexpected and rare adverse events may occur if Gardasil becomes more widely administered.<sup>41</sup>

Because HPV Types 16 and 18 cause seventy percent of cervical cancer cases, Gardasil could substantially reduce the incidence of HPV-associated cervical cancer.<sup>42</sup> Proponents of mandatory HPV vaccination argue that this potential, along with the knowledge that there is currently no other way to prevent HPV transmission among the sexually active population, supports large-scale vaccination of pre-adolescents and adolescents before they become sexually active.<sup>43</sup> However, longer follow-up studies will be needed to assess the safety and duration of

---

33. FDA Press Release, *supra* note 28.

34. Stan L. Block et al., *Comparison of the Immunogenicity and Reactogenicity of a Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, and 18) L1 Virus-Like Particle Vaccine in Male and Female Adolescents and Young Adult Women*, 118 PEDIATRICS 2135, 2135 (2006).

35. *Id.* at 2144.

36. FDA Press Release, *supra* note 28.

37. Villa et al., *supra* note 21, at 277; see also Danice K. Eaton et al., *Youth Risk Behavior Surveillance—United States, 2005*, 55 MORBIDITY & MORTALITY WKLY. REP. 1, 19 (2006) (“Nationwide, 6.2% of students had had sexual intercourse for the first time before age 13 years.”).

38. Block et al., *supra* note 34, at 2141; Villa et al., *supra* note 21, at 277.

39. Block et al., *supra* note 34, at 2141–42. Significantly more subjects in the group of boys and girls experienced fevers, compared to subjects in the group of sixteen- to twenty-three-year-old females. *Id.* at 2143. However, most fevers (96.4 percent) were low grade and of short duration. *Id.*

40. *Id.* at 2141.

41. U.S. FOOD & DRUG ADMIN., PRODUCT APPROVAL INFORMATION—LICENSING ACTION, GARDASIL® QUESTIONS AND ANSWERS, <http://www.fda.gov/cber/products/hpvmer060806qa.htm> (last visited Aug. 16, 2007).

42. Villa et al., *supra* note 21, at 271; FDA Press Release, *supra* note 28.

43. Villa et al., *supra* note 21, at 277.

efficacy, as well as to determine whether booster doses of the HPV vaccine are necessary.<sup>44</sup>

### C. *The Debate Regarding Mandatory Vaccination*

Based on the results of these clinical trials, the federal Food and Drug Administration (FDA) approved Gardasil for use in females nine to twenty-six years old.<sup>45</sup> The FDA recommended that the vaccine be given as three injections over a six-month period.<sup>46</sup> Soon after its approval, the United States Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend that the new HPV vaccine routinely be given to girls when they are eleven and twelve years old.<sup>47</sup> Additionally, the ACIP noted that the vaccine may be administered to girls as young as nine years old at the discretion of the child's physician or health care provider.<sup>48</sup> The ACIP recommendations also allow for vaccination of girls and women between ages thirteen and twenty-six because, according to the ACIP, this age group may benefit from getting the vaccine even though many of them may have engaged in sexual activity prior to vaccination.<sup>49</sup>

Now that the HPV vaccine has acquired the widespread backing of both the ACIP and the FDA, states have begun to consider implementation strategies for HPV vaccination.<sup>50</sup> On the one hand, the benefits of HPV vaccination include reductions in HPV infection, cervical cancer incidence, and death.<sup>51</sup> Furthermore, the HPV vaccine has the potential to reduce the economic, emotional, and psychological burden of dealing with an incurable sexually transmitted infection and developing cancer.<sup>52</sup>

---

44. *Id.*

45. FDA Press Release, *supra* note 28.

46. *Id.*

47. Press Release, Office of Enter. Comm'n, Ctrs. for Disease Control & Prevention, CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination (June 29, 2006), <http://www.cdc.gov/od/oc/media/pressrel/r060629.htm> [hereinafter CDC Press Release]. "The ACIP, consisting of 15 members appointed by the Secretary of the Department of Health and Human Services (HHS), advises the director of CDC and Secretary of HHS on control of vaccine-preventable diseases and vaccine usage." *Id.* "Recommendations of the ACIP become CDC policy when they are accepted by the director of CDC and are published in CDC's Morbidity and Mortality Weekly Report (MMWR)." *Id.* However, the ACIP makes only recommendations, as there are no federal laws requiring the immunization of children. *Id.*

48. *Id.*

49. *Id.*

50. *See infra* Part III.A.

51. Zimmerman, *supra* note 7, at 4813.

52. *See* Inmaculada de Melo-Martín, *The Promise of the Human Papillomavirus Vaccine Does Not Confer Immunity Against Ethical Reflection*, 11 ONCOLOGIST 393, 395 (2006) (discussing the "emotional and psychological burden of dealing with a sexually transmitted infection and of developing cancer").

On the other hand, the long-term effects of the HPV vaccine are unknown, and widespread vaccination might reveal a rare adverse reaction not previously seen.<sup>53</sup> Further, although the vaccine produces a strong immune response, it is unclear how long this response will last.<sup>54</sup> Because the duration of immunity is unknown, this uncertainty could affect whether physicians recommend “booster doses” and calls into question the cost-effectiveness of the vaccine.<sup>55</sup> Finally, because of the current prevalence of HPV infection and the fact that the vaccine is only effective before HPV infection occurs, the vaccine’s effect on cervical cancer rates will be delayed by at least fifteen years.<sup>56</sup>

In addition to concerns about the long-term safety and efficacy of the new HPV vaccine, many social conservative groups strongly oppose making the vaccine mandatory for girls as a condition to school entry.<sup>57</sup> Advocates of this position believe that the decision whether to vaccinate a child against this or other sexually transmitted infections should remain with the child’s parent.<sup>58</sup> HPV is an infectious disease that is primarily acquired and transmitted by sexual contact.<sup>59</sup> As a result, those opposing mandatory vaccination feel that a school requirement for HPV vaccinations might encourage adolescent sexual activity and send a subtle message condoning premarital sex.<sup>60</sup>

In contrast, groups working to reduce the morbidity and mortality rates of cervical cancer want the vaccine to be part of the standard roster of shots that pre-adolescent girls receive just before reaching puberty.<sup>61</sup> In fact, Juan Carlos Felix of the University of Southern California in Los Angeles, who leads the National Cervical Cancer Coalition’s medical advisory panel, “would like to see it that if you don’t have your HPV vaccine, you can’t start high school.”<sup>62</sup> The Director of the CDC’s National Center for Immunization and Respiratory Diseases, Dr. Anne

---

53. Zimmerman, *supra* note 7, at 4813.

54. Roden & Wu, *supra* note 24, at 756. Several large ongoing studies are poised to address this issue, and two intermediate-term studies have been conducted. *Id.* At three and a half years after vaccination, protection against persistent HPV Type 16 infection remained at ninety-four percent compared with 100 percent at seventeen months. *Id.* Another study showed 94.3 percent protection against persistent HPV infection at four and a half years after vaccination. *Id.*

55. Zimmerman, *supra* note 7, at 4818.

56. Roden & Wu, *supra* note 24, at 758.

57. *E.g.*, Press Release, Family Research Council, FRC Issues Statement on Development of HPV Vaccines (Oct. 18, 2005), <http://www.frc.org/get.cfm?i=PR05J04>; CHRISTIAN MED. & DENTAL ASS’NS, VACCINE PREVENTS CERVICAL CANCER (2005), <http://www.cmdahome.org/index.cgi?BISKIT=343567272&CONTEXT=art&art=3241>; FOCUS ON THE FAMILY, FOCUS ON THE FAMILY POSITION STATEMENT: HUMAN PAPILLOMAVIRUS VACCINES (2007), [http://www.family.org/sharedassets/correspondence/pdfs/PublicPolicy/Position\\_Statement-Human\\_Papillomavirus\\_Vaccine.pdf](http://www.family.org/sharedassets/correspondence/pdfs/PublicPolicy/Position_Statement-Human_Papillomavirus_Vaccine.pdf).

58. Zimmerman, *supra* note 7, at 4817.

59. CDC FACT SHEET, *supra* note 6.

60. Stein, *supra* note 5.

61. *Id.*

62. *Id.*



Schuchat, stresses that the new HPV vaccine represents an important medical breakthrough that addresses a major health problem for women and represents a significant advance in women's health.<sup>63</sup>

Amidst this growing debate and increasing media attention, individual states are being forced to decide whether the HPV vaccine should be mandatory or voluntary and, if mandatory, at what age to begin vaccinating pre-adolescent girls. Because of the controversy surrounding the HPV vaccine, it is only a matter of time before courts will be required to enter the debate. Historically, courts have allowed mandatory vaccination against infectious diseases to protect the public health.<sup>64</sup> However, unlike the other infectious diseases considered in these cases, such as measles and smallpox, HPV is primarily transmitted by sexual contact.<sup>65</sup> Although strong arguments exist on both sides of the mandatory vaccination issue, because the HPV vaccine is not analogous to other infectious disease vaccines and various long-term safety and efficacy issues have not been adequately addressed, mandatory HPV vaccination as a condition for school entry is not justified at this time.

## II. MANDATORY HPV VACCINATION: LEGAL ISSUES

Although laws mandating vaccination as a condition for school entry are widely accepted,<sup>66</sup> the new HPV vaccine has sparked controversy regarding whether states can and should require HPV vaccination for pre-adolescent girls as a condition for school entry. Subparts A and B discuss the history and evolution of mandatory vaccination laws and, in particular, mandatory HIV testing for at-risk individuals. These subparts also explain why analogies between the HPV vaccine and other infectious disease vaccines, as well as comparisons to mandatory HIV testing for at-risk individuals, are inappropriate. In addition, subpart C discusses the necessity of informed consent for medical decision-making and how this concept relates to the new HPV vaccine.

### A. *Is the HPV Vaccine Analogous to Other Infectious Disease Vaccines?*

#### 1. *The History and Evolution of Mandatory Vaccination Laws*

States have authority to mandate vaccination of citizens through what are traditionally known as "police powers."<sup>67</sup> The term "police powers" refers to the

---

63. CDC Press Release, *supra* note 47.

64. See *infra* Part II.A.1.

65. Zimmerman, *supra* note 7, at 4815.

66. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 857-58 (2001-02).

67. James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 319 (1997-98).

broad powers retained by states, pursuant to the Tenth Amendment of the Constitution, to regulate matters affecting the health, safety, and general welfare of the public.<sup>68</sup> Police powers allow states to perform a wide range of governmental actions in the interest of public health, including mandatory vaccinations.<sup>69</sup>

In 1827, Boston became the first city to implement mandatory vaccination policies for children attending public schools.<sup>70</sup> Over two decades later, states began to enact their own mandatory school vaccination laws, including Massachusetts in 1855, New York in 1862, and Connecticut and Pennsylvania in 1872 and 1895, respectively.<sup>71</sup> “The trend toward compulsory child vaccination as a condition of school attendance eventually spread to states in the Midwest . . . South . . . and the West.”<sup>72</sup>

The most significant decision regarding a challenge to mandatory vaccination laws was *Jacobson v. Massachusetts*, in which the Supreme Court upheld the constitutionality of a law requiring smallpox vaccinations in the city of Cambridge.<sup>73</sup> The Court stated that:

[T]he police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety. . . . [T]he liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. . . . Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.<sup>74</sup>

However, the *Jacobson* Court also acknowledged limits on the states’ police powers.<sup>75</sup> Laws establishing mandatory vaccinations are constitutionally permissible if exercised in conformity with the principles of: (1) Public Health Necessity—the police powers must be based on the “necessities of the case” and cannot be exercised in “an arbitrary, unreasonable manner” or “go so far beyond what was reasonably required for the safety of the public”<sup>76</sup>; (2) Reasonable Means—the Court in *Jacobson* introduced a test requiring a reasonable relationship

---

68. *Id.* at 318-19.

69. *Id.* at 323-25.

70. Hodge & Gostin, *supra* note 66, at 851.

71. *Id.*

72. *Id.*

73. 197 U.S. 11 (1905); see also Chari Alson Maddren, *AIDS Vaccines: Balancing Human Rights with Public Health*, 17 TEMP. INT’L & COMP. L.J. 277, 284 (2003) (describing *Jacobson* as “[t]he seminal case on the right of the state to enforce a compulsory vaccination law”).

74. *Jacobson*, 197 U.S. at 25-27.

75. Hodge & Gostin, *supra* note 66, at 856.

76. *Jacobson*, 197 U.S. at 28.

between the public health intervention and the achievement of a legitimate public health objective.<sup>77</sup> Although the objective of the state legislature may be valid and beneficent, the methods adopted must have a “real or substantial relation” to protection of the public health and cannot merely be a “plain, palpable invasion of rights”<sup>78</sup>; (3) Proportionality—the police powers of the state “may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression.”<sup>79</sup> Consequently, a mandatory vaccination law may be unconstitutional if it is “gratuitously onerous or unfair”<sup>80</sup>; and (4) Harm Avoidance—while those who pose a risk to the community can be required to submit to compulsory measures, including vaccination, for the common good, the measure itself should not pose a health risk to the individual.<sup>81</sup> Requiring a person to be immunized despite knowing that the immunization may cause harm would be “cruel and inhuman in the last degree.”<sup>82</sup> Therefore, states have the power to require vaccination for the public good, but this power must be exercised in a reasonable manner in order “to avoid constitutional scrutiny.”<sup>83</sup>

Although mandatory school vaccination laws infringe on the parents’ right to choose what is best for their child, these laws have been “widely accepted and judicially sanctioned.”<sup>84</sup> However, state legislatures have carved out exceptions to school vaccination requirements. For example, “[a]ll states permit medical exemptions for individuals who are immunocompromised, have allergic reactions to vaccine constituents, have moderate or severe illness, or other medical contraindications to vaccination.”<sup>85</sup> Also, in most states children are exempt from immunization if their parents can show that vaccinations are against their religious

---

77. *Id.* at 26.

78. *Id.* at 31; see *Nebbia v. New York*, 291 U.S. 502, 525 (1934) (finding that a public welfare regulation must not be “unreasonable, arbitrary or capricious, and that the means selected shall have a real and substantial relation to the object sought to be attained”).

79. *Jacobson*, 197 U.S. at 38.

80. Hodge & Gostin, *supra* note 66, at 856.

81. *Jacobson*, 197 U.S. at 38-39.

82. *Id.*

83. Hodge & Gostin, *supra* note 66, at 857.

84. *Id.* at 857-58; see, e.g., *Zucht v. King*, 260 U.S. 174, 177 (1922) (upholding a local government mandate for vaccination as a prerequisite for public school attendance); *Globe Sch. Dist. No. 1 v. Bd. of Health*, 179 P. 55, 56, 61 (Ariz. 1919) (ordering a school to be closed for failure to comply with mandatory vaccination laws); *State v. Zimmerman*, 90 N.W. 783, 783, 786 (Minn. 1902) (denying an unvaccinated child admission to school); *People v. Ekerold*, 105 N.E. 670, 670, 672-73 (N.Y. 1914) (imposing criminal sanctions on parents who failed to send their children to school because they did not meet the vaccination requirements); *State v. Bd. of Educ.*, 60 P. 1013, 1017-18 (Utah 1900) (upholding the power of the school board to deny an unvaccinated child admission to school).

85. Daniel A. Salmon, *Mandatory Immunization Laws and the Role of Medical, Religious and Philosophical Exemptions 1* (Oct. 2003) (unpublished commentary, on file with the Johns Hopkins Bloomberg School of Public Health), <http://www.vaccinesafety.edu/exemptreview101503.pdf>.

beliefs.<sup>86</sup> However, courts generally construe religious exemptions strictly, insisting that the belief against compulsory vaccination must be genuine, sincere, and an integral part of the religious doctrine.<sup>87</sup> Finally, some states allow ethical or philosophical exemptions that are not based on spiritual or religious grounds.<sup>88</sup>

## 2. *The HPV Vaccine vs. Traditional Infectious Disease Vaccines*

Since the landmark case of *Jacobson v. Massachusetts*, courts have uniformly held that states have the power to mandate vaccination of their citizens.<sup>89</sup> However, in all of these cases, the vaccine in question targeted a disease that could easily be transmitted to all members of the community.<sup>90</sup> Thus, it is difficult to predict how courts might rule with regard to mandatory vaccination of pre-adolescent girls with the new HPV vaccine.

The HPV vaccine is readily distinguishable from other mandatory vaccines. First, "HPV is primarily transmitted by sexual contact," which implicates "lifestyle choices and behavioral decisions."<sup>91</sup> By contrast, measles and smallpox, diseases that gave rise to other mandatory school vaccination laws, can easily spread to others through the air or by casual contact.<sup>92</sup> As a result, "other children would be

---

86. Hodge & Gostin, *supra* note 66, at 859. All states except for Mississippi and West Virginia allow religious exemptions to mandatory vaccinations. Salmon, *supra* note 85, at 1.

87. *Mason v. Gen. Brown Cent. Sch. Dist.*, 851 F.2d 47, 51-52 (2d Cir. 1988) (denying an exemption based on personal beliefs rather than religious convictions); *Brown v. City Sch. Dist.*, 429 N.Y.S.2d 355, 357 (N.Y. App. Div. 1980) (finding that there must be a sincerity of religious belief and no "clear and present danger of the particular communicable disease"); *McCartney v. Austin*, 293 N.Y.S.2d 188, 199 (N.Y. App. Div. 1968) (distinguishing moral conviction as a result of religious training from moral conviction outside of religion); *In re Elwell*, 284 N.Y.S.2d 924, 932 (N.Y. App. Div. 1967) (denying an exemption for a student whose religion posed no objections to immunization).

88. Salmon, *supra* note 85, at 1. Currently, nineteen states allow for personal or philosophical exemptions. *Id.*

89. *See, e.g., Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944) ("The right to practice religion freely does not include liberty to expose the community or the child to communicable disease . . ."); *Zucht*, 260 U.S. at 176 (noting that it was well-settled that it is within the police power of a state to provide for compulsory vaccination); *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 886-88 (Ark. 1951) (holding that the requirement of compulsory vaccination is not "arbitrary, capricious and unreasonable," and does not deprive a citizen of liberty guaranteed by the Constitution); *Cram v. Sch. Bd.*, 136 A. 263, 263 (N.H. 1927) (holding that laws related to vaccination present questions for the legislature and not the courts); *Maricopa County Health Dep't v. Harmon*, 750 P.2d 1364, 1368 (Ariz. Ct. App. 1987) (stating that the health department had authority to adopt reasonably necessary measures to prevent and control communicable diseases, and to prohibit school attendance by any child who had not been immunized); *State v. Bd. of Educ.*, 204 N.E.2d 86, 89 (Ohio Ct. App. 1963) (holding that a school board had full authority to compel immunization by making and enforcing rules and regulations to secure immunizations); *McSween v. Bd. of Sch. Trs.*, 129 S.W. 206, 208 (Tex. Civ. App. 1910) (holding that a school board order excluding pupils from school who refused vaccination, and who were not already vaccinated, did not deprive the pupils of liberty without due process).

90. Michael Sanzo, *Vaccines and the Law*, 19 PEPP. L. REV. 29, 32 (1991).

91. Zimmerman, *supra* note 7, at 4815.

92. *Id.*

at risk from an infected child merely by the infected child's presence in the classroom."<sup>93</sup> Furthermore, the HPV vaccine does not protect against all strains of HPV that can cause cervical cancer,<sup>94</sup> and all women receiving the vaccine must still continue to have regular cervical screenings (Pap tests) at least once every three years.<sup>95</sup> Finally, the HPV vaccine is only approved for use in girls and women.<sup>96</sup> As a result, unlike other compulsory immunizations, only girls will be required to comply with mandatory HPV vaccination laws.<sup>97</sup>

Because HPV may be distinguished from other infectious diseases for which states have required vaccination as a condition for school entry, it is difficult to determine how courts will rule regarding state legislation requiring pre-adolescent girls to receive the HPV vaccine before being allowed to enter the sixth grade. Debates surrounding mandatory HIV testing may provide insight into whether courts would allow states to implement mandatory HPV vaccination laws because HPV, like HIV, is a sexually transmitted infection that disproportionately affects certain segments of the population.

### *B. Mandatory HIV Testing for At-Risk Individuals*

#### *1. Background of Mandatory HIV Testing*

States have enacted mandatory HIV testing laws in order to protect healthy individuals against the risks created by third parties.<sup>98</sup> Generally, a state's police powers are broadly construed "where the state is protecting third parties from risks created by individual conduct."<sup>99</sup> As such, courts have been willing to uphold mandatory HIV testing in situations where there is a high probability of HIV transmission.<sup>100</sup> For example, courts have required prostitutes and other criminal sex offenders to submit to HIV testing because these individuals, if infected, are

---

93. *Id.*

94. See FDA Press Release, *supra* note 28.

95. Brenda E. Sirovich & H. Gilbert Welch, *The Frequency of Pap Smear Screening in the United States*, 19 J. GEN. INTERNAL MED. 243, 243 (2004); CTRS. FOR DISEASE CONTROL & PREVENTION, REDUCING RISK: HUMAN PAPILLOMAVIRUS (HPV) (2007), [http://www.cdc.gov/cancer/cervical/basic\\_info/reducing\\_risk.htm](http://www.cdc.gov/cancer/cervical/basic_info/reducing_risk.htm) [hereinafter CDC HPV FACT SHEET].

96. CDC HPV FACT SHEET, *supra* note 95.

97. The legal and ethical issues on gender inequality raised by mandatory HPV vaccination laws are beyond the scope of this paper. For a general discussion of these issues, see de Melo-Martín, *supra* note 52.

98. See A. Alyce Werdel, *Mandatory AIDS Testing: The Legal, Ethical and Practical Issues*, 5 NOTRE DAME J.L. ETHICS & PUB. POL'Y 155, 199 n.288 (1990) (discussing states that require those convicted of sexual offenses to undergo HIV testing).

99. *Id.* at 198.

100. Matthew J. Mitten, *AIDS and Athletics*, 3 SETON HALL J. SPORT L. 5, 17 (1993).

likely to transmit HIV to third parties.<sup>101</sup> Further, drug users and prisoners have also been forced to undergo mandatory HIV testing in order to prevent widespread transmission of HIV among these high-risk populations.<sup>102</sup> On the other hand, courts are reluctant to uphold mandatory HIV testing for individuals at low risk of contracting or transmitting HIV.<sup>103</sup>

“Although a wide range of federal and state constitutional objections have been raised against [mandatory HIV] testing, these challenges have almost uniformly been rejected” when the individual is at high risk for transmitting HIV to others.<sup>104</sup> For example, in *Adams v. State*, a Georgia court held that a statute permitting involuntary HIV testing for individuals convicted of sexual offenses or crimes involving the risk of significant exposure to HIV did not constitute an unreasonable search or seizure and did not violate an individual’s fundamental right to privacy.<sup>105</sup>

## 2. HPV Vaccination vs. HIV Testing

Of course, mandatory HIV testing for individuals at high risk of contracting or transmitting HIV is readily distinguishable from mandatory HPV vaccination of pre-adolescent girls who have not yet engaged in sexual intercourse. On the one hand, the HPV vaccine targets pre-adolescent girls who have not yet engaged in sexual activity, a population that is at low risk for contracting or transmitting HPV.<sup>106</sup> Therefore, mandatory HPV vaccination for pre-adolescent girls is not analogous to mandatory HIV testing for at-risk individuals because these pre-adolescent girls pose no immediate danger to others.

---

101. *Id.*; see *People v. Adams*, 597 N.E.2d 574, 580-82 (Ill. 1992) (finding that the state has a compelling interest in protecting public health and that the HIV test is a reasonable intrusion to accomplish those ends); *Love v. Super. Ct.*, 276 Cal. Rptr. 660, 664 (Cal. Ct. App. 1990) (holding that a California statute requiring the testing of prostitutes for HIV served an “obvious and compelling ‘special need’”).

102. Mitten, *supra* note 100, at 17-18; see, e.g., *Harris v. Thigpen*, 941 F.2d 1495, 1500-01 (11th Cir. 1991) (noting that the Department of Corrections may require inmates to undergo HIV testing and separate those who test positive from the general prison population without violating any privacy rights); *Dunn v. White*, 880 F.2d 1188, 1195-96 (10th Cir. 1989) (holding that a nonconsensual AIDS test did not violate a prisoner’s First or Fourth Amendment rights because “the prison has a substantial interest in pursuing a program to treat those infected with [HIV] and in taking steps to prevent further transmission”); *People v. C.S.*, 583 N.E.2d 726, 730 (Ill. App. Ct. 1991) (holding that a statute requiring persons convicted of unauthorized possession of a hypodermic needle or syringe to undergo mandatory HIV testing was constitutional).

103. Mitten, *supra* note 100, at 18; see, e.g., *Doe v. Roe*, 526 N.Y.S.2d 718, 725 (N.Y. App. Div. 1988) (“[A] showing of compelling need [ ] must be met before an involuntary test for [HIV] may be ordered.”).

104. Robin Cheryl Miller, Annotation, *Validity, and Propriety Under Circumstances, of Court-Ordered HIV Testing*, 87 A.L.R.5th 631, 644 (2001).

105. *Adams v. State*, 498 S.E.2d 268, 271-72 (Ga. 1998).

106. See *Eaton et al.*, *supra* note 37, at 19.

On the other hand, HIV and HPV are sexually transmitted infections that disproportionately affect discrete segments of the population.<sup>107</sup> HIV is contracted by more men than women, causing a higher mortality rate among men, and HPV is readily contracted and transmitted by both men and women, but only women can develop cervical cancer from persistent HPV infection.<sup>108</sup> Further, both HIV and HPV-associated cervical cancer create substantial public health risks.<sup>109</sup>

Although HIV and HPV have similar characteristics, mandatory HIV testing has never been upheld in courts when the circumstances involved individuals who were at a low risk for contracting and transmitting HIV.<sup>110</sup> Given the fact that states want to mandate HPV vaccination for pre-adolescent girls who have not yet engaged in sexual activity, analogies between mandatory HIV testing for at-risk individuals and mandatory HPV vaccination cannot be strongly supported. As with mandatory HIV testing laws, courts may not be willing to uphold mandatory HPV vaccination given the low overall risk of infection and transmission in the target population.

### C. *The Necessity of Informed Consent*

Mandating HPV vaccination for pre-adolescent girls as a condition for school entry also raises informed consent issues. The doctrine of informed consent assumes that an individual is free to exercise his or her free will when making important decisions concerning medical treatment and care.<sup>111</sup> At common law, an individual could consent to health care if this consent was voluntary, knowing, and competent.<sup>112</sup> The Supreme Court recognized constitutional support for informed consent in *Cruzan v. Missouri Department of Health*, holding that "[t]his notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment."<sup>113</sup>

The doctrine of informed consent in medical treatment decisions can be broken down into five elements: (1) Disclosure; (2) Comprehension; (3) Voluntariness; (4) Competence; and (5) Consent.<sup>114</sup> Although many commentators

---

107. S.H. Ebrahim et al., *Sexual Behaviour: Related Adverse Health Burden in the United States*, 81 SEXUALLY TRANSMITTED INFECTIONS 38, 38, 39 tbl.1 (2005).

108. *Id.*

109. *Id.* at 39-40.

110. See *supra* note 103 and accompanying text.

111. Simon N. Whitney et al., *A Typology of Shared Decision Making, Informed Consent, and Simple Consent*, 140 ANN. INTERNAL MED. 54, 54, 56 (2004).

112. See Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & L. 249, 253 (1995-96) (stating that an individual gives informed consent if he or she receives a thorough disclosure, comprehends this disclosure, is competent to act and acts voluntarily, and consents).

113. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990).

114. Severyn, *supra* note 112, at 253.

have discussed informed consent as it relates to medical procedures, not much has been published on informed consent for vaccination.<sup>115</sup> In part, this may be due to the fact that vaccinations are not given the same deference by courts as other medical interventions.

“[F]or the most part, an immunization encounter is a voluntary request by the patient” or, if the patient is a child, by their parents or guardians, “for protection against future disease.”<sup>116</sup> However, laws that mandate vaccination as a condition for attending school necessarily diminish the voluntary nature of immunizations.<sup>117</sup> If the parent is no longer able to refuse vaccinations for their child, “a basic component of informed consent is absent.”<sup>118</sup> “Parents wishing to enroll their child in school” are, therefore, left with few choices, and the child is effectively required to receive all CDC-recommended vaccines.<sup>119</sup> Although many people support mandatory vaccinations as a condition for school entry,<sup>120</sup> some “[o]rganized groups of parents and consumer advocates . . . argue that the government should never impose vaccination, with its attendant risks of injury and disease, without informed consent.”<sup>121</sup>

The issue with regard to the HPV vaccine is whether states should effectively remove a parent’s right to informed consent in order to vaccinate pre-adolescent girls against a sexually transmitted infection that cannot be transmitted through the air or by casual contact. Even though HPV-associated cervical cancer is a public health risk,<sup>122</sup> many parents may feel that the choice to engage in sexual activity is a private matter<sup>123</sup> and that, as such, parents should be able to decide if and when their daughters receive the vaccine. Because the HPV vaccine is new, the long-term effects of the vaccine, as well as the duration of its efficacy, are unknown.<sup>124</sup> By

---

115. *Id.* at 255.

116. *Id.* (quoting Vincent A. Fulginiti, *Informed Consent in Immunization Practice*, in *IMMUNIZATION IN CLINICAL PRACTICE* 29, 30 (Vincent A. Fulginiti ed., 1982)).

117. *Id.* (quoting Fulginiti, *supra* note 116, at 30).

118. *Id.*

119. *Id.* at 273.

120. *See supra* Part II.A.1.

121. Hodge & Gostin, *supra* note 66, at 876.

122. *See* Ebrahim et al., *supra* note 107, at 39-40 (noting that twenty million people carry HPV and that “[c]ervical cancer causes more deaths than HIV”).

123. *See* Sonya Sorich, *Bill Mandating HPV Vaccine Ignites Debate*, LEDGER-ENQUIRER (Columbus, Ohio), Mar. 1, 2007, at A1, available at <http://www.ledger-enquirer.com/mld/ledgerenquirer/news/local/16806370.htm> (noting that such a vaccination is a “government interference in [a] private matte[r]”); *Maker of Cervical Cancer Vaccine Stops Pushing to Require It for Girls*, VOICE AM. NEWS, Feb. 23, 2007, <http://www.voanews.com/specialenglish/2007-02-23-voa1.cfm> (finding that there are people who believe mandating the HPV vaccination would “violate privacy rights”).

124. *See* Zimmerman, *supra* note 7, at 4813 (“[L]ong-term . . . protection afforded by vaccination is not yet known due to relatively recent development of the HPV vaccines. . . . Potential harms include



contrast, children have received other mandatory vaccines for decades and, consequently, any adverse effects have been well-documented.<sup>125</sup> These distinctions lead to the conclusion that pre-adolescent girls should not be vaccinated for HPV without the informed consent of their parents.

Although mandatory vaccination laws require parents to sacrifice their right to decide what is best for their child, proponents of such laws argue that this sacrifice is reasonable in order to protect the health of the public. A parent's decision not to vaccinate their child is not consistent with the public policy goal of protecting the entire community from disease.<sup>126</sup> HPV is readily transmissible, with at least fifty percent of sexually active men and women acquiring genital HPV infection at some point in their lives.<sup>127</sup> Further, there is no cure once a person becomes infected with HPV.<sup>128</sup>

Because Gardasil is an important advance in the fight against cervical cancer,<sup>129</sup> advocates of mandatory vaccination may argue that parental consent is not necessary. Indeed, affording individuals the right of informed consent to vaccinate their daughters against HPV may not be for the greatest good of the community. However, given that HPV is primarily transmitted through sexual contact and not through the air or by casual contact, parents may be justified in feeling that they should be able to weigh the risks and benefits of HPV vaccination and to decide if and when their daughter is vaccinated.

---

adverse reactions . . . ."); see Roden & Wu, *supra* note 24, at 756 (discussing the lack of clarity regarding how long HPV vaccines provide protection).

125. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., DIPHTHERIA, TETANUS & PERTUSSIS VACCINES: WHAT YOU NEED TO KNOW (2001), *available at* <http://www.cdc.gov/nip/publications/VIS/vis-dtp.pdf> (listing the mild to severe potential risks of the DTaP vaccine); CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., MEASLES, MUMPS & RUBELLA VACCINES: WHAT YOU NEED TO KNOW (2003), *available at* <http://www.cdc.gov/nip/publications/VIS/vis-mmr.pdf> (reviewing the mild, moderate, and severe problems with the MMR vaccine); CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., POLIO VACCINE: WHAT YOU NEED TO KNOW (2000), *available at* <http://www.cdc.gov/nip/publications/VIS/vis-IPV.pdf> (noting that the risks associated with polio vaccine are minimal).

126. Hodge & Gostin, *supra* note 66, at 877.

127. CDC FACT SHEET, *supra* note 6.

128. See *id.* (noting that there is no "cure" for HPV infection, only treatments to deal with symptoms caused by HPV infection).

129. FDA Press Release, *supra* note 28.

### III. MANDATORY HPV VACCINATION AS A CONDITION FOR SCHOOL ENTRY IS PREMATURE

#### A. *Proposed Legislation*

As of July 11, 2007, twenty-four states and the District of Columbia have introduced bills mandating HPV vaccination for pre-adolescent girls as a condition for school entry.<sup>130</sup> Although most proposed state laws would permit parents to receive an exemption for medical, religious, or personal reasons,<sup>131</sup> the legislation seeks to ensure that most girls are vaccinated before becoming sexually active.<sup>132</sup> For example, Michigan Senate Bill 1417, the first bill proposed on the issue of mandatory HPV vaccination, required that all girls entering the sixth grade in a public or private school, be immunized with the HPV vaccine beginning in the 2008-2009 school year.<sup>133</sup> However, girls whose parents have medical, philosophical, or religious oppositions to the vaccine would be exempt.<sup>134</sup> In addition, parents would have the right to elect not to immunize their child under an explicit opt-out provision.<sup>135</sup> Parents choosing not to have the vaccine administered to their daughter would have to sign a form stating that they received information about the link between HPV and cervical cancer.<sup>136</sup> This bill passed the Michigan Senate by a wide margin, but met opposition from parents and other opponents to mandatory vaccination and, ultimately, failed in the Michigan House of Representatives.<sup>137</sup>

Although the Michigan bill was defeated, other states have proposed similar legislation.<sup>138</sup> For example, California and South Carolina have both introduced legislation that would require girls entering the sixth grade to receive the HPV vaccine before being admitted to public or private schools, and South Carolina's legislation would allow parents the opportunity to opt out if they do not want their

---

130. NAT'L CONFERENCE OF STATE LEGISLATURES, HPV VACCINE: INTRODUCED LEGISLATION 2007, <http://www.ncsl.org/programs/health/HPVvaccine.htm#hpvlegis> (last visited July 31, 2007).

131. *See supra* Part II.A.1.

132. Melissa Hendricks, *HPV Vaccine: Who Chooses?*, L.A. TIMES, Feb. 5, 2007, at F1.

133. S. 1417, 2006 Leg., 93rd Sess. (Mich. 2006).

134. *See* SENATE FISCAL AGENCY, MICH. SENATE, BILL ANALYSIS (2006); Leslie Baldacci, *Lawmaker Champions Cancer Vaccine, Reveals Her Story: Sen. Halvorson Says Inoculation Against HPV Ought to Be Law*, CHI. SUN TIMES, Sept. 22, 2006, at 48.

135. *See* S. 1417, 2006 Leg., 93rd Sess. (Mich. 2006) (allowing parents the option of not having their child receive the HPV vaccine by submitting a signed statement to the child's school).

136. *Id.*

137. Martin, *supra* note 2. In 2007, Michigan again introduced mandatory HPV vaccination bills, but no action had been taken by the time of publication. NAT'L CONFERENCE OF STATE LEGISLATURES, *supra* note 130.

138. Hendricks, *supra* note 132.

daughter to receive the vaccine.<sup>139</sup> Virginia has also proposed legislation requiring all females entering the sixth grade to receive the HPV vaccine.<sup>140</sup>

It is too soon to predict whether any of the proposed legislation will be successful.<sup>141</sup> So far, only two mandatory HPV vaccination bills have passed out of state legislatures, in Virginia and New Mexico.<sup>142</sup> The Michigan bill passed the Senate with an overwhelming majority but was narrowly defeated in the House.<sup>143</sup> Similarly, Maryland introduced a mandatory HPV vaccination bill, but its chief sponsor, Sen. Delores Kelley, withdrew it following criticism from parents and groups opposed to the legislation.<sup>144</sup> The Maryland bill, which required sixth grade girls to be vaccinated against HPV, had strong legislative backing with almost half of the state senators signing onto it.<sup>145</sup> Mandatory HPV vaccination bills also failed to pass in Colorado, Florida, Kentucky, and West Virginia, but similar bills are still pending in fourteen states and in the District of Columbia.<sup>146</sup>

Texas Governor Rick Perry, “[a]verting a potentially divisive debate,” implemented a mandatory HPV vaccination program by circumventing the state legislature.<sup>147</sup> On February 2, 2007, Governor Perry signed an executive order mandating HPV vaccination of all girls aged eleven and twelve who are entering the sixth grade, beginning in September 2008.<sup>148</sup> Under this executive order, parents may opt out of the vaccination program “for reasons of conscience, including religious beliefs.”<sup>149</sup> In response to Governor Perry’s actions, the Texas legislature passed a bill rescinding the executive order.<sup>150</sup> It remains to be seen, however, whether other state governors will follow Perry’s lead in order to implement mandatory HPV vaccination programs that otherwise may not pass state legislatures.

---

139. Assemb. 16, 2007-08 Leg., Reg. Sess. (Cal. 2006) (amended Feb. 9, 2007); H. 3136, 2007-08 Gen. Assemb., 117th Sess. (S.C. 2007).

140. S. 1230, 2007 Gen. Assemb., Reg. Sess. (Va. 2007).

141. Hendricks, *supra* note 132.

142. *Kaine Will Sign Bill to Require HPV Vaccinations*, RICHMOND TIMES DISPATCH, Mar. 2, 2007, at B8. Governor Kaine has promised to sign the mandatory HPV vaccination bill into law. *Id.* However, other states considering mandatory HPV vaccination bills have not been as successful. The New Mexico bill, for example, was vetoed. NAT’L CONFERENCE OF STATE LEGISLATURES, *supra* note 130.

143. Martin, *supra* note 2.

144. Tom LoBianco, *O’Malley Seeks More for Schools*, WASH. TIMES, Feb. 1, 2007, at B3.

145. Ovetta Wiggins, *Sponsor to Pull Measure Mandating HPV Vaccine*, WASH. POST, Jan. 31, 2007, at B5.

146. NAT’L CONFERENCE OF STATE LEGISLATURES, *supra* note 130.

147. Blumenthal, *supra* note 4.

148. *See id.*; Governor of the State of Texas, Exec. Order RP65 (Feb. 2, 2007), <http://www.governor.state.tx.us/divisions/press/exorders/rp65>.

149. *Id.*

150. *See* H.B. 1098, 80th Legis., Reg. Sess. (Tex. 2007); NAT’L CONFERENCE OF STATE LEGISLATURES, *supra* note 130.

Also coming under increasing scrutiny are many lawmakers' motives behind the push for mandatory HPV vaccination laws. Merck, the developer of Gardasil, initiated a nationwide lobbying campaign to convince state lawmakers to pass legislation requiring the HPV vaccine as a condition for school entry.<sup>151</sup> For example, Merck contributed close to \$40,000 to political campaigns in Virginia in 2005 and 2006.<sup>152</sup> In Texas, Governor Perry has been accused of being influenced by his former chief of staff, who is now a lobbyist for Merck, in connection with the issuance of the executive order that made Texas the first state to mandate the Gardasil vaccine as a condition for school entry.<sup>153</sup> There is no question that Merck has a powerful financial incentive to push for state mandates.<sup>154</sup> Indeed, Merck probably would like the HPV vaccine to be mandatory for school entry before GlaxoSmithKline's HPV vaccine, Cervarix, is FDA-approved, in order for Merck to establish the dominant market position.<sup>155</sup> However, Merck was forced to suspend its lobbying efforts in February 2007 amid increasing pressure from parents and medical groups who feel that requiring the vaccine is premature.<sup>156</sup>

### B. Perspectives on School Vaccination Requirements

Proponents of mandatory vaccination as a condition for school entry contend that comprehensive and standardized vaccination policies benefit both children and the community as a whole.<sup>157</sup> As such, advocates favoring school vaccination policies, including state legislators and public health officials,<sup>158</sup> would like the HPV vaccine to become part of the standard roster of shots that children, particularly girls, receive before puberty.<sup>159</sup>

By contrast, opponents of school vaccination policies assert that mandatory vaccination is unnecessary for diseases in which the risk of harm due to the vaccination outweighs the risk of contracting the disease.<sup>160</sup> Consequently, opponents believe that the government should not impose mandatory vaccination policies until the safety and efficacy of the vaccine is fully known.<sup>161</sup>

---

151. Amy Gardner, *Drugmaker Assists in Pushing for Mandate for HPV Vaccination*, WASH. POST, Feb. 11, 2007, at C5.

152. *Id.*

153. *Id.*

154. *See id.*

155. *Id.* The projected FDA approval of GSK's Cervarix is between October 2007 and January 2008. *GlaxoSmithKline Files for FDA Approval of HPV Vaccine Cervarix*, MED. NEWS TODAY (Apr. 3, 2007), <http://www.medicalnewstoday.com/medicalnews.php?newsid=66788>.

156. Linda A. Johnson, *Drugmaker Suspends Cancer Shot Lobbying*, CHI. TRIB., Feb. 21, 2007, at 3.

157. Hodge & Gostin, *supra* note 66, at 875.

158. *Id.*

159. Stein, *supra* note 5.

160. Hodge & Gostin, *supra* note 66, at 835-36, 876.

161. John Carreyrou, *Moves to Vaccinate Girls for Cervical Cancer Draw Fire*, WALL ST. J., Feb. 7, 2007, at D1-D2.

Opponents to mandatory HPV vaccination stress that they support the HPV vaccine as important in the fight against cervical cancer, but oppose state laws requiring HPV vaccination as a condition for school entry.<sup>162</sup> In particular, socially conservative groups fear that because the HPV vaccine protects against a sexually transmitted infection, it may send a subtle message to pre-adolescents and adolescents condoning sexual activity before marriage.<sup>163</sup> Because conservative groups feel that administering the HPV vaccine to young girls conflicts with their message on abstinence, they contend that parents, not the state, should have the right to choose whether their child receives the HPV vaccine.<sup>164</sup> The Family Research Council, a group of social conservatives, issued a position statement on the new HPV vaccine:

Because parents have an inherent right to be the primary educator and decision-maker regarding their children's health, we would oppose any measures to legally require vaccination or to coerce parents into authorizing it. Because the cancer-causing strains of HPV are not transmitted through casual contact, there is no justification for any vaccination mandate as a condition of public school attendance. However, we do support the widespread distribution and use of vaccines against HPV.<sup>165</sup>

Other socially conservative groups, such as Focus on the Family and the Christian Medical and Dental Associations, also support widespread distribution of the HPV vaccine but oppose making the vaccine mandatory as a condition for school entry.<sup>166</sup>

Nevertheless, proponents of mandatory vaccination also contend that compulsory vaccination programs have significantly increased the frequency of childhood immunizations.<sup>167</sup> However, it is difficult to ascertain whether this effect is the direct result of school vaccination requirements.<sup>168</sup> Other factors may have substantially contributed to this increase in vaccination rates.<sup>169</sup> For instance, public health initiatives focused on non-compulsory methods of compliance are

---

162. Stein, *supra* note 5.

163. *Id.*

164. Zimmerman, *supra* note 7, at 4817.

165. FAMILY RESEARCH COUNCIL, FAMILY RESEARCH COUNCIL STATEMENT REGARDING HPV VACCINES (Feb. 21, 2006), <http://www.frc.org/get.cfm?i=LH06B03> (last visited Aug. 16, 2007) (on file with author).

166. Focus on the Family, *supra* note 57; Christian Med. & Dental Ass'ns, From News & Views: 10-13-05, <http://www.cmdahome.org/index.cgi?BISKIT=0&CONTEXT=art&art=3241> (citing Rita Rubin, *Vaccine Prevents Cervical Cancer*, USA TODAY, Oct. 6, 2005) (last visited Aug. 16, 2007).

167. Hodge & Gostin, *supra* note 66, at 878. It has been demonstrated that mandatory vaccination laws increase immunization rates by fifteen percent. Kathryn M. Edwards, *State Mandates and Childhood Immunization*, 284 JAMA 3171, 3172 (2000).

168. Hodge & Gostin, *supra* note 66, at 878.

169. *Id.* at 880.

increasing.<sup>170</sup> In addition, education through public health organizations or health care providers regarding the risks and benefits of vaccination may encourage parents to voluntarily vaccinate their children.<sup>171</sup>

In the case of HPV vaccination, there is strong evidence that most parents are in favor of vaccinating their daughters.<sup>172</sup> In a California study, researchers found that seventy-five percent of parents do support HPV vaccination by the recommended age of thirteen and that eighty-two percent of parents support vaccination by the age of sixteen.<sup>173</sup> Further, “the majority of parents from all racial-ethnic groups, both genders, all income and educational levels, and all religious denominations” supported vaccination in the California study.<sup>174</sup> Similarly, surveys given to women in Texas with children between the ages of eight and fourteen indicated that sixty-seven percent of respondents who had a daughter, and sixty-six percent of respondents who had a son, would consent to have their child vaccinated.<sup>175</sup> The Texas study did not find any “differences in the patterns of acceptance when participants were grouped by education level, religion, race, income, or other demographic factors.”<sup>176</sup> These studies suggest that sufficient levels of vaccination can occur without mandatory HPV vaccination laws.<sup>177</sup>

Proponents of mandatory vaccination also raise the argument that school immunization policies allow economically disadvantaged children access to vaccinations that they cannot otherwise afford.<sup>178</sup> Gardasil is an expensive vaccine, costing \$360 for the recommended series of three doses.<sup>179</sup> However, because the new HPV vaccine is ACIP-recommended,<sup>180</sup> public funds may be used to vaccinate the poorest children.<sup>181</sup> Medicaid law specifically codifies immunizations as a

---

170. *Id.*

171. *Id.*

172. Press Release, Pub. Health Inst., Most California Parents Support New HPV Vaccine According to New Study (Dec. 13, 2006), available at [http://www.marketwire.com/mw/release\\_html\\_b1?release\\_id=194686](http://www.marketwire.com/mw/release_html_b1?release_id=194686).

173. *Id.*

174. *Id.*

175. Brian M. Slomovitz et al., *Are Women Ready for the HPV Vaccine?*, 103 GYNECOLOGIC ONCOLOGY 151, 152 (2006).

176. *Id.* at 153.

177. “Because of the benefits of herd immunity, vaccinating even a relatively small portion of the target population leads to substantial decreases in disease prevalence . . . relative to prevaccination rates.” Al V. Taira et al., *Evaluating Human Papillomavirus Vaccination Programs*, 10 EMERGING INFECTIOUS DISEASES 1915, 1918 (2004).

178. Arthur Allen, *And Now, the HPV Vaccine*, SLATE, June 8, 2006, <http://www.slate.com/id/2143304/>.

179. Gardner, *supra* note 151.

180. CDC Press Release, *supra* note 47.

181. Cynthia Dailard, *The Public Health Promise and Potential Pitfalls of the World's First Cervical Cancer Vaccine*, 9 GUTTMACHER POL'Y REV. 6, 7 (2006), available at <http://www.guttmacher.org/pubs/gpr/09/1/gpr090106.pdf>.

mandatory component of the Medicaid program for individuals under the age of twenty-one who otherwise qualify for Medicaid, and Medicaid specifies that this coverage be in accordance with ACIP standards.<sup>182</sup> Additionally, the federally funded Vaccines for Children Program (VFC) creates a federal entitlement to immunization services for children aged eighteen and under who are (1) Medicaid eligible; (2) uninsured; (3) underinsured; or 4) Native American or Alaska Natives.<sup>183</sup> As a result of these federal laws, the new HPV vaccine is available to the most vulnerable children, whether or not individual states make it a mandatory condition for school entry.

### C. *Proposed Recommendation for HPV Vaccine Implementation*

Mandatory HPV vaccination laws as a condition for school entry are premature and do not adequately address important legal and policy implications. Therefore, the best course of action is to make the HPV vaccine completely voluntary, requiring parents to give specific permission before their child is vaccinated via an “opt-in provision.” This approach would allow parents to have complete control over whether their daughter receives the new HPV vaccine.

New Hampshire has implemented a voluntary HPV vaccine program, with plans to vaccinate 63,000 girls aged eleven to eighteen over the next four years.<sup>184</sup> The New Hampshire program encourages parents to take more responsibility and “to make choices that are in the best interest of their children.”<sup>185</sup> The program incorporates educational efforts aimed at schools, pediatricians’ offices, and the community.<sup>186</sup> Instead of offering parents an opt-out provision for mandatory HPV vaccination, “[i]n New Hampshire, parents opt in.”<sup>187</sup> Greg Moore, a spokesman for the New Hampshire Department of Health and Human Services states, “[w]e are at the beginning of the process, but from the anecdotal evidence, there appears to be a great demand from parents.”<sup>188</sup> New Hampshire’s success in implementing a voluntary HPV vaccination program suggests that mandatory vaccination laws are not the only way to ensure that girls receive the HPV vaccine.

In order for voluntary HPV vaccination programs to be successful, however, physicians and public health officials must educate parents about the HPV vaccine as well as the link between HPV and cervical cancer, so that they can adequately

---

182. 42 U.S.C. § 1396s(a)(1) (2000); *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, ACIP VFC VACCINE RESOLUTIONS, *available at* [http://www.cdc.gov/nip/vfc/acip\\_vfc\\_resolutions.htm](http://www.cdc.gov/nip/vfc/acip_vfc_resolutions.htm) (defining the ACIP standards) (last visited Aug. 16, 2007).

183. 42 U.S.C. § 1396s(b)(2) (2000).

184. Courtland Milloy, *Force Is Not the Only Way to Administer a Vaccine*, WASH. POST, Jan. 24, 2007, at B01.

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

weigh the risks of the vaccine with the potential benefits. Accordingly, national health organizations should develop educational materials for health care providers that “offer guidance about how to discuss HPV vaccination with parents” and children, as well as advice regarding how to handle parental refusals of HPV vaccination.<sup>189</sup>

#### CONCLUSION

Proposed state legislation requiring mandatory HPV vaccination for pre-adolescent girls as a condition for school entry raises unique legal and social issues. Specifically, requiring HPV vaccination as a condition for entry “raises broad questions about the acceptability of mandatory public health measures, the scope of parental autonomy, and the role of political advocacy in determining how preventive health measures are implemented.”<sup>190</sup>

Mandatory HPV vaccination policies may not be legally sound. First, analogies drawn between mandatory vaccination programs for infectious diseases that are easily transmissible through the air or by casual contact and infectious diseases that are primarily transmitted through sexual contact cannot be supported. Likewise, mandatory HIV testing for at-risk individuals and mandatory HPV vaccination for pre-adolescent girls at no risk of transmitting HPV to others are easily distinguishable. Mandatory vaccination also effectively takes away parents’ right to choose whether their daughters should receive a vaccine that protects against a sexually transmitted infection, and for which the duration of effectiveness and any possible long-term adverse effects are still unknown.

Debates surrounding the implementation of mandatory HPV vaccination have also caused a clash between health advocates, who seek to reduce the incidence of cervical cancer, and social conservatives who believe that the decision to vaccinate should rest with parents. Strong arguments exist on both sides. However, because questions remain about the long-term safety and efficacy of the HPV vaccine, parents, instead of the state, should be able to weigh the risks and benefits of vaccination and to ultimately decide whether their daughters should receive the vaccine.

Because mandatory HPV vaccination is not supported by sound legal or policy justifications, the vaccine should only be administered to girls on a voluntary basis with the specific consent of the parents. Fortunately, this may be feasible because the HPV vaccine has been widely accepted by parents, and studies suggest that sufficient levels of vaccination can occur without mandatory vaccination laws. In addition, through Medicaid and other publicly funded mechanisms, the HPV

---

189. Daley et al., *supra* note 26, at 2286.

190. James Colgrove, *The Ethics and Politics of Compulsory HPV Vaccination*, 355 NEW ENG. J. MED. 2389, 2391 (2006).



vaccine will be available to those who cannot afford the costs associated with administering the vaccine, even if states do not require the vaccination as a condition for school entry. Therefore, until the HPV vaccine has been tested further to determine its long-term adverse effects and its effectiveness in preventing cervical cancer, states should not mandate the HPV vaccine as a condition for school attendance.