

“Please, Don’t Shot My Daughter!” Is There Legal Support for State-compelled HPV Vaccination Laws? Why Ethical, Moral, and Religious Opposition to These Laws May Be Jumping the Gun*

I. INTRODUCTION

On June 8, 2006, the Food and Drug Administration announced its “approval of Gardasil[®], the first vaccine developed to prevent cervical cancer” caused by human papillomavirus (HPV), a sexually transmitted infection.¹ Shortly thereafter, on June 29, the Centers for Disease Control’s Advisory Committee on Immunization Practices (ACIP) announced its recommendation that girls between the ages of eleven and twelve be vaccinated against HPV.² In response to the ACIP’s recommendation, several states are considering, or have considered, mandatory vaccinations as a prerequisite for both public and private school admittance.³ As of June 2008, Virginia is the only state with such a mandate enacted into law.⁴ This legislation has sparked a nation-wide debate that, thus far, has focused primarily on the ethical, moral, and

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1. 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 (June 8, 2006), <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html> [hereinafter FDA Licenses New Vaccine].

2. Press Release, Centers for Disease Control and Prevention, CDC’s Advisory Committee Recommends Human Papillomavirus Vaccination (June 29, 2006), <http://www.cdc.gov/od/oc/media/pressrel/r060629.htm> [hereinafter CDC Recommends HPV Vaccination].

3. National Conference of State Legislatures, *HPV Vaccine: HPV Vaccine Legislation*, Updated June 4, 2008, <http://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited July 1, 2008).

4. *Id.* The Virginia HPV vaccine mandate goes into effect October 1, 2008. VA. CODE ANN. § 32.1-46(A)(12) (2007). However, Virginia is currently considering a bill that would amend and reenact § 32.1-46 of the Virginia Code to remove the HPV vaccination mandate. S.B. 722, 2008 Leg., Reg. Sess. (Va. 2008), available at <http://leg1.state.va.us/cgi-bin/legp504.exe?081+ful+SB722+pdf>.

religious opposition to compulsory HPV vaccination as a prerequisite for school admittance. However, few have examined whether there is even legal support for these proposed mandates in the first place, which raises the question: are we jumping the gun?

In this Comment, I will establish that there is no legal support for state-mandated HPV vaccination laws because these mandates extend beyond a state's power to compel vaccination as granted by the Supreme Court in *Jacobson v. Massachusetts*⁵ and are in contravention of the U.S. Constitution. In Part II.A, I discuss HPV, its relationship to cervical cancer, and the HPV Vaccine, Gardasil[®]. In Part II.B, I discuss the origins of state-compelled vaccination laws as a prerequisite for school admittance. In Part II.C, I discuss the constitutionality of state-compelled vaccination laws, and finally in Part II.D, I discuss the available exemptions from many of these compulsory vaccination laws.

In Part III.A, I analyze the authority of states to compel the HPV vaccine and argue that these proposed mandates lack legal support because they extend beyond the powers granted by the Supreme Court in *Jacobson*. In Part III.B, I analyze the constitutionality of state-mandated HPV vaccination laws and argue that they further lack legal support because the laws violate due process by interfering with parents' constitutional right to regulate their children's sexual behavior as they see fit and deny equal protection because the vaccine currently is required only for young women. In addition, I explain why exemptions from the mandates will not solve these constitutional issues because the exemptions themselves are likely unconstitutional and undermine public immunization—the very thing mandatory vaccination laws are designed to create. In Part III.C, I suggest that states should not enact laws mandating the HPV vaccine. Instead, I suggest that states should take an educational approach and enact laws requiring that parents and their daughters receive information about HPV, its relationship to cervical cancer, and prevention methods, including the HPV vaccine. In addition, I suggest that states should implement school-run HPV vaccination programs, which would provide the vaccine at a minimal cost to those girls whose parents choose to opt-in to the program.

5. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

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II. BACKGROUND

A. HPV, Cervical Cancer, and Gardasil[®]

1. HPV

A recent study conducted by researchers at the federal Centers for Disease Control sent a sobering message to parents in the United States: at least one in four teenage girls in this country has a sexually transmitted disease.⁶ The study also revealed that, of the infections for which the study tested, HPV was the most common.⁷ HPV “is the most common sexually transmitted infection in the United States.”⁸ There are approximately forty different strains of HPV.⁹ As of 2006, over 20 million men and women in the United States were infected with HPV, with that number rising at a rate of 6.2 million each year.¹⁰

For the majority of those infected with HPV, the disease eventually goes away on its own without ever causing health problems.¹¹ In fact, of those once infected, most likely were unaware they were carriers of the disease because the majority of people infected with HPV never develop symptoms.¹² Approximately 15% of the U.S. population is currently infected with HPV.¹³ However, because the disease can, and often does, go away on its own, the percentage of the population that will contract HPV at some point in their lifetime, in comparison to the percentage of those currently infected, is staggering—more than 80% of sexually active women will contract some form of genital HPV by the time they are

6. Associated Press, *1 in 4 Teen Girls Has Sexually Transmitted Disease: Virus that Causes Cervical Cancer Most Common, Government Study Finds*, MSNBC.COM, March 11, 2008, <http://www.msnbc.msn.com/id/23574940/>.

7. *Id.*

8. CDC Recommends HPV Vaccination, *supra* note 2.

9. Renee Gerber, *Mandatory Cervical Cancer Vaccinations*, 35 J.L. MED. & ETHICS 495, 495 (2007).

10. CDC Recommends HPV Vaccination, *supra* note 2.

11. Centers for Disease Control and Prevention, *Vaccines: VPD-VAC/HPV/Vaccine Safety and Efficacy Q&A*, June 28, 2007, <http://www.cdc.gov/vaccines/vpd-vac/hpv/hpv-vacsafe-effic.htm> [hereinafter *Vaccines: Safety and Efficacy Q&A*].

12. Rebecca E. Skov, *Examining Mandatory HPV Vaccination for All School-Aged Children*, 62 FOOD & DRUG L.J. 805, 806 (2007).

13. *Id.*

fifty¹⁴ and at least 50% of all sexually active persons will contract some form of HPV during their lifetimes.¹⁵

2. Cervical Cancer

Although HPV does not cause health problems for a majority of those infected, the results can be devastating when it does. HPV is a “necessary cause” of all cervical cancers,¹⁶ meaning “cervical cancer does not and will not develop in the absence of the persistent presence of HPV DNA.”¹⁷ This causal link between HPV and cervical cancer was first conclusively established in 2000. In the public health context, this discovery is as important as the discovery of the link between cigarette smoking and lung cancer.¹⁸

All cancers are caused when abnormal cells grow rapidly in the body.¹⁹ When these abnormal cells grow in a woman’s cervix, the disease is called “cervical cancer.”²⁰ Worldwide, cervical cancer is the second leading cause of cancer death for women.²¹ Recently in the United States, however, the rates of cervical cancer have drastically declined due to the prevalence of preventative care like the Pap test.²² The Pap test is an effective method of prevention because it detects abnormal changes in cervical cells so that they may be removed before cancer develops.²³ Though the rates of cervical cancer in the United States continue to decline, each year approximately 10,000 women are newly diagnosed with cervical cancer and 3700 women die from the disease.²⁴

14. Centers for Disease Control and Prevention, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practice (ACIP)*, 56 MORBIDITY & MORTALITY WEEKLY REPORT 1, 4 (2007), available at <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf> [hereinafter MMWR].

15. Skov, *supra* note 12, at 806.

16. MMWR, *supra* note 14, at 4.

17. F.X. Bosch et al., *The Causal Relation Between Human Papillomavirus and Cervical Cancer*, 55 J. CLINICAL PATHOLOGY 244, 244 (2002).

18. *Id.*

19. Centers for Disease Control and Prevention, *Basic Information about Cervical Cancer*, Updated March 14, 2008, http://www.cdc.gov/cancer/cervical/basic_info/.

20. *Id.*

21. *HPV Vaccine: HPV Vaccine Legislation*, *supra* note 3.

22. Skov, *supra* note 12, at 806.

23. *Id.*

24. *HPV Vaccine: HPV Vaccine Legislation*, *supra* note 3.

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3. Gardasil[®]

The HPV vaccine Gardasil[®] is extremely effective against four HPV strains: two that cause genital warts and two that cause approximately 70% of all cervical cancers.²⁵ However, Gardasil[®] is a preventative vaccine, in that it is only effective in persons who have not yet contracted the HPV strains the vaccine is designed to prevent.²⁶ It is therefore recommended that girls receive the vaccine before they become sexually active and at risk of HPV exposure.²⁷ The FDA licensed Gardasil[®] for use by females between the ages of nine and twenty-six;²⁸ however, the ACIP recommends that girls be vaccinated between the ages of eleven and twelve.²⁹

B. The History of State-Compelled Vaccination as a Prerequisite for Public and Private School Admittance

1. The Origins of Vaccination

State-compelled vaccination laws are traceable to extremely crude beginnings. The earliest known form of inoculation was accomplished via variolation—the process of deliberately infecting a non-infected individual with smallpox by transferring the virus directly from an infected individual.³⁰ The first inoculation performed in this country was likely in 1721, when Dr. Zabdiel Boylston inoculated 246 individuals in Boston, Massachusetts using the variolation method.³¹ Although six of his patients later died from the inoculation, subjecting Boylston to ridicule from many of his peers, Dr. Boylston's remaining patients all survived when a smallpox epidemic later devastated the city.³²

25. See Gerber, *supra* note 9, at 495 (“The HPV vaccine protects against four strains of HPV: two low-risk strains that cause genital warts and two high-risk strains that cause pre-cancers.”); CDC Recommends HPV Vaccination, *supra* note 2 (stating that Gardasil “is highly effective against four types of the HPV virus, including two that cause about 70 percent of cervical cancer”).

26. See CDC Recommends HPV Vaccination, *supra* note 2 (noting “the vaccine should be administered before the onset of sexual activity (i.e., before women are exposed to the viruses)”).

27. Vaccines: Safety and Efficacy Q&A, *supra* note 11.

28. *Id.*

29. CDC Recommends HPV Vaccination, *supra* note 2.

30. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 836 (2002).

31. Michael Sanzo, *Vaccines and the Law*, 19 PEPP. L. REV. 29, 29 (1991); Hodge & Gostin, *supra* note 30, at 839.

32. Hodge & Gostin, *supra* note 30, at 838–840.

In 1796, Dr. Edward Jenner, often called the “Father of Vaccination,” introduced a new form of inoculation in England, which, unlike variolation, was based on scientific principals and did not pose as high of a risk of death.³³ Jenner discovered that patients inoculated with material extracted from the sores of humans infected with the animal disease cowpox, were effectively immunized against smallpox as well.³⁴ Jenner’s method was later named a “vaccine,” derived from the Latin word *vaccinus*, which literally translates as “pertaining to cows.”³⁵ Knowledge of Dr. Jenner’s vaccination soon spread, ultimately leading to the vaccination movement in the United States during the early 1800s.

2. The Origins of Mandatory School Vaccination Laws

During the vaccination movement, lawmakers in the United States started to consider compulsory vaccination as a viable solution to control the smallpox epidemic.³⁶ By happenstance, the rise in smallpox that triggered these legislative considerations coincided with the rise in compulsory education policies.³⁷ “[Because] the bringing together of large numbers of children clearly facilitated the spread of smallpox, and [because] vaccination provided a relatively safe preventive, it was natural that compulsory school attendance laws should lead to a movement for compulsory vaccination.”³⁸ In 1827, Boston became the first city to mandate the vaccination of schoolchildren as a prerequisite for public school attendance when it required that all children present proof of vaccination prior to entering the public school system.³⁹ Several states, including the Commonwealth of Massachusetts, soon followed Boston’s lead, enacting their own statewide school vaccination mandates during the last half of the 19th century.⁴⁰

Though many states enacted compulsory vaccination laws by the start of the 20th century, the Supreme Court had yet to consider whether states could legally enact such laws. A chain of events stemming from a law passed in Cambridge, Massachusetts in 1902, however, would change this, setting the stage for the Supreme Court’s landmark decision

33. *Id.* at 839.

34. *Id.*

35. *Id.* at 840.

36. *Id.* at 850.

37. *Id.*

38. *Id.* (quoting John Duffy, *School Vaccination: The Precursor to School Medical Inspection*, 33 J. HIST. MED. 344, 345 (1978)).

39. *Id.* at 851.

40. *Id.*

in *Jacobson v. Massachusetts*, where the Court affirmatively established a state's right to compel vaccination.

In 1902, the Cambridge board of health passed a law requiring all citizens who had not received vaccinations in the preceding five years to be re-vaccinated.⁴¹ This law was passed in response to a Massachusetts state law, which provided that:

“the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit \$5.”⁴²

To enforce its new law, the Cambridge board of health authorized Dr. E. Edwin Spencer, the chairman of the Cambridge board of health, to compel vaccination of Cambridge residents free of charge.⁴³ While visiting Cambridge residents, Spencer offered to vaccinate the Reverend Henning Jacobson; Jacobson, however, refused.⁴⁴ Though Spencer informed Jacobson that if he refused the vaccination he would face a five dollar fine, Jacobson continued to refuse the vaccination and refused to pay the fine.⁴⁵ Jacobson's refusals set the course for a legal battle that ended at the Supreme Court in 1905, earning him the title as “the most famous opponent of vaccination in U.S. history.”⁴⁶

Jacobson v. Massachusetts marked the first time the Supreme Court considered the constitutionality of state-compelled vaccination laws.⁴⁷ Jacobson argued the vaccination mandate violated his Fourteenth Amendment rights because it abridged his privileges as a citizen of the United States and deprived him of liberty without due process.⁴⁸ The Court however, disagreed, stating that “the 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

41. JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 38 (University of California Press 2006).

42. *Jacobson v. Massachusetts*, 197 U.S. 11, 12 (1905) (quoting chap. 75 § 137 of The Revised Laws of Massachusetts Commonwealth).

43. *Jacobson*, 197 U.S. at 13; COLGROVE, *supra* note 41, at 38.

44. COLGROVE, *supra* note 41, at 38.

45. *Id.*

46. *Id.* at 40.

47. Sanzo, *supra* note 31, at 31.

48. *Jacobson v. Massachusetts*, 197 U.S. 11, 13–14 (1905).

all circumstances, wholly freed from restraint.”⁴⁹ In addition to finding that the compulsory vaccination law did not violate Jacobson’s due process rights, the Court also held that the authority to impose mandatory vaccination laws fell within the confines of a state’s police power because “the 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.”⁵⁰ Ultimately, the Court concluded that the mandatory vaccination law did not violate the Constitution, which affirmatively established a state’s right to compel vaccination.

Seventeen years later in *Zucht v. King*,⁵¹ the Supreme Court extended *Jacobson* to the compulsory vaccination of schoolchildren. Rosalyn Zucht argued that a San Antonio city ordinance mandating the vaccination of schoolchildren as a prerequisite for public and private school attendance violated her due process rights after she was excluded from school for failure to present the required vaccination certificate.⁵² The Court, however, disagreed and upheld the constitutionality of the ordinance, finding that it did not confer “arbitrary power, but [rather] only that broad discretion required for the protection of the public health.”⁵³

C. *Constitutionality of State Compelled Vaccination Laws*

1. Due Process

Pursuant to the Due Process Clause of the Fourteenth Amendment, a state may not “deprive any person of life, liberty, or property, without due process of law.”⁵⁴ Following *Jacobson*, opponents of compelled vaccination argued that state-mandated vaccination laws, as a prerequisite for school admittance specifically, deprived the unvaccinated child of his or her liberty and property without due process of law.⁵⁵ This argument failed in the courts, however, with one court

49. *Id.* at 26.

50. *Id.* at 25. The Court defined a state’s “police power” as “a power [that] the state did not surrender when becoming a member of the Union under the Constitution.” *Id.*

51. 260 U.S. 174 (1922).

52. *Id.* at 175.

53. *Id.* at 177.

54. U.S. Const. amend. XIV, § 1.

55. *See, e.g.,* Seubold v. Fort Smith Special Sch. Dist., 237 S.W.2d 884, 885 (Ark. 1951) (where the plaintiffs argued that the compulsory vaccination law as a prerequisite for school attendance was “so arbitrary, capricious and unreasonable that its enforcement against the said

even going so far as to state that “[t]he contention that [a school vaccination mandate] is inconsistent with the liberty guaranteed by the federal and state Constitutions has been too completely repelled by the opinion of the Supreme Court of the United States in *Jacobson v. Massachusetts* to [even] justify further discussion.”⁵⁶

Although traditional compulsory vaccination laws as a prerequisite for public and private school admittance have consistently been held not in derogation of due process, a vaccination law directed against a disease spread by sexual contact presents new and unexplored due process issues. The Supreme Court has “recognized on numerous occasions that the relationship between parent and child is constitutionally protected”⁵⁷ and that the “freedom of personal choice in matters of . . . family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment.”⁵⁸ How best to regulate a child’s sexual behavior falls within these boundaries and, as such, parents have a constitutional right to regulate their child’s sexual behavior as they see fit.⁵⁹ When ascertaining whether a state-mandated policy violates this right, one must ask two questions: (1) Is the policy supported by a compelling state interest? (2) If so, is the policy *essential* to serving that state interest?⁶⁰ Thus, “the issue is not one of purpose but one of effect” and courts “must take great care not to be blinded by the concept that the end justifies the means.”⁶¹

Based on the foregoing, a three-step inquiry is appropriate when evaluating whether a state mandated policy violates due process: (1) Does the policy intrude on a constitutionally protected right?; (2) If so, is there a compelling state interest to justify that intrusion?; and finally, (3) Is the policy in question absolutely necessary to meet that compelling state interest?

plaintiffs would amount to a deprivation of their liberty and property without due process of law”); *New Braunfels v. Waldschmidt*, 207 S.W. 303, 307 (Tex. 1918) (“The minor defendants in error claim[ed] that they [had] property rights in state and local school funds, of which they would be deprived, without due process of law, by the enforcement of the ordinance.”).

56. *Waldschmidt*, 207 S.W. at 306 (citation omitted).

57. *Quilloin v. Walcott*, 434 U.S. 246, 255 (1977) (citing *Wisconsin v. Yoder*, 406 U.S. 205, 231–233 (1972); *Stanley v. Illinois*, 405 U.S. 645 (1972); *Meyer v. Nebraska*, 262 U.S. 390, 399–401 (1923)).

58. *Quilloin*, 434 U.S. at 255 (1977) (quoting *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 639–40 (1974)).

59. *Alfonso v. Fernandez*, 606 N.Y.S.2d 259, 265 (N.Y. App. Div. 1993).

60. *Id.* (emphasis added).

61. *Id.* at 266.

2. Equal Protection

Under the Equal Protection Clause of the Fourteenth Amendment, a state may not deny its citizens the equal protection of its laws.⁶² Therefore, “[c]lass legislation, discriminating against some and favoring others, is prohibited; [however,] legislation which, in carrying out a public purpose, is limited in its application, if within the sphere of its operation it affects alike all persons similarly situated, is not within the amendment.”⁶³ For this reason, arguments that mandatory school vaccination laws violate the Equal Protection Clause because they favor others to the detriment of schoolchildren have failed because such laws are limited in their application and, within that application apply equally to all schoolchildren insofar as the vaccination requirements are concerned.⁶⁴ Furthermore, the argument that mandatory school vaccination laws violate the Equal Protection Clause because they favor vaccinated schoolchildren to the detriment of unvaccinated schoolchildren by excluding unvaccinated children from attending school has also failed.⁶⁵ As the Supreme Court stated in *Zucht v. King*, “in the exercise of the police power reasonable classification may be freely applied, and [a] regulation is not violative of the equal protection clause merely because it is not all-embracing.”⁶⁶ While arguments that mandatory vaccination laws violate the Equal Protection Clause of the Fourteenth Amendment have failed in the past on grounds that such laws treat all schoolchildren equally, a vaccination law directed only at female schoolchildren may prove more contentious.

The Equal Protection Clause prohibits the government from intentionally discriminating against members of a protected class.⁶⁷ When a state statute explicitly classifies individuals on the basis of gender, it is subject to intermediate scrutiny under the Equal Protection Clause.⁶⁸ A “party seeking to uphold a statute that classifies individuals on the basis of their gender must carry the burden of showing an ‘*exceedingly* persuasive justification’ for the classification.”⁶⁹ To

62. U.S. Const. amend. XIV, § 1.

63. *Barbier v. Connolly*, 113 U.S. 27, 32 (1884).

64. *E.g.*, *French v. Davidson*, 77 P. 663 (Cal. 1904).

65. See NEWTON EDWARDS, *THE COURTS AND THE PUBLIC SCHOOLS: THE LEGAL BASIS OF SCHOOL ORGANIZATION AND ADMINISTRATION* 574–75 (The University of Chicago Press 1971) (1933) (discussing the circumstances under which the courts will sustain legislation).

66. *Zucht v. King*, 260 U.S. 174, 177 (1922).

67. *Hodge & Gostin*, *supra* note 30, at 861.

68. 16B C.J.S. *Constitutional Law* § 1140 (2007).

69. *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982) (quoting *Kirchberg v.*

determine whether the proffered justification for sex-based discrimination in a state statute is “exceedingly persuasive,” a two-part analysis is necessary. First, the proponent must show that the sex-based classification serves an “important governmental objective[.]”⁷⁰ If this first prong is satisfied, the proponent must then show “that the discriminatory means employed’ are ‘*substantially* related to the achievement of [that governmental] objective.”⁷¹ If this test is not met, the statute violates the Equal Protection Clause of the Fourteenth Amendment.

D. Exemptions from State-Compelled Vaccination Laws

Although most state-compelled vaccination laws are considered “mandatory,” there are a number of exemptions available from nearly all state-compelled vaccination laws. There are three basic categories of vaccination exemptions: (1) medical exemptions; (2) religious exemptions; and (3) philosophical exemptions. Medical exemptions are available for those whose health or life would be jeopardized by the particular vaccine.⁷² Religious exemptions are available for those whose religious beliefs prohibit them from receiving vaccinations.⁷³ Finally, philosophical exemptions, which were developed out of the religious exemptions, are available for those who have “moral, personal, or philosophical objection[s] . . . to vaccinations.”⁷⁴

Currently, all fifty states offer medical exemptions,⁷⁵ forty-seven states offer religious exemptions,⁷⁶ and seventeen states offer philosophical exemptions.⁷⁷

Feenstra, 450 U.S. 455, 461 (1981) (emphasis added)).

70. *Hogan*, 458 U.S. at 724 (quoting *Wengler v. Druggists Mutual Ins. Co.*, 446 U.S. 142, 150 (1980)).

71. *Id.* (emphasis added).

72. Sean Coletti, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1342 (2004).

73. *Id.* at 1343.

74. *Id.*

75. See Steve P. Calandrillo, *Vanishing Vaccinations: Why Are so Many Americans Opting out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 433 (2004) (“No regulation should require vaccination where the harm imposed is greater than the benefit received.”).

76. Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 282 (2003).

77. *Id.* at 283.

IV. ANALYSIS

The development and subsequent approval of the HPV vaccine marked a milestone for the medical community. As one doctor remarked, “[w]e use “breakthrough” way too often, but this is a breakthrough.”⁷⁸ However, the buzz surrounding the vaccine quickly turned from excitement to worry when states began to consider mandating the vaccine for young girls as a prerequisite for school admittance. Only a minority of parents in the United States would support such mandates.⁷⁹ The House of Representatives echoed this sentiment in July 2007, when it passed a bill that, if passed into federal law, would ban states that enact these mandates from using federal money to help fund the vaccine⁸⁰—an effective threat considering “Gardasil[®] is the most expensive pediatric vaccine ever marketed.”⁸¹ The concerns stemming from the proposed mandates center on an all-too-familiar debate: “the balance between government’s obligation to safeguard the health of its people and the rights of individuals to make their own decisions about matters affecting their health and their children’s health.”⁸²

There is no legal support for strict state-mandated HPV vaccination programs. Although mandatory vaccination as a prerequisite for public and private school admittance is not a novel concept,⁸³ mandating the HPV vaccine poses new concerns not raised by traditional school mandated vaccines. For instance, state HPV vaccination mandates will mark the first time, for the majority of states, that a vaccination is

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

79. *Majority of U.S. Parents Not in Favor of HPV Vaccine Mandates*, VACCINE WEEKLY, June 6, 2007, at 8.

80. Gregory Lopes, *House Rejects Shots for HPV*, WASH. TIMES, July 20, 2007, at C8. This legislation passed as an amendment offered by Congressman Phil Gingrey, M.D. to the Labor, Health, and Human Services, Education Appropriations bill. However, “Representative Gingrey has also introduced H.R. 1153, the Parental Right to Decide Protection Act, to address this concern.” US Federal News, *House Passes Rep. Gingrey Amendment to Keep HPV Vaccination Family Decision*, July 18, 2007.

81. Robert F. Onder, Op-Ed., *As I See It: Robert F. Onder on HPV Vaccinations*, K.C. STAR, Aug. 14, 2007, at B8.

82. Hendricks, *supra* note 78.

83. See Hodge & Gotin, *supra* note 30, at 851 (“In 1827, Boston became the first city to require all children entering the public schools to give evidence of vaccination.” (citing John Duffy, *School Vaccination: The Precursor to School Medical Inspection*, 33 J. HIST. MED. 344 (1978))).

mandated for a non-communicable disease.⁸⁴ Moreover this is the first time a vaccination mandate would only affect one gender.⁸⁵

Strictly mandating HPV vaccination extends beyond the limits established by the Supreme Court in *Jacobson v. Massachusetts* and is in contravention of the Constitution. Moreover, while exemptions may seem like a logical way to solve these problems, this option is equally contentious because of the unconstitutional nature of such exemptions and their overall effect on the goals of vaccination mandates. As such, states should not adopt laws mandating that young girls receive the HPV vaccine as a prerequisite for school admittance.

A. *State-Compelled HPV Vaccinations Extend Beyond the Powers Granted by the Supreme Court in Jacobson v. Massachusetts*

Because HPV is not transmitted via casual contact and the vaccine is not essential to protect the public from HPV and cervical cancer, mandating HPV vaccination as a prerequisite for both public and private school admittance extends beyond the powers granted to the states by the Supreme Court in *Jacobson v. Massachusetts*.

1. HPV Lacks the Imminent Danger Posed to All Segments of the Population that Justified Compulsory Vaccination in *Jacobson*

Although the Supreme Court affirmatively held that it is within a state's police powers to compel vaccination, the *Jacobson* decision is not without limits. To understand the Court's decision, it is important to read *Jacobson* in light of its historical context. At that time, the imminent threat of smallpox was very real. As evidence, the Court spoke only of the authority of a state "to determine for all what ought to be done in . . . an *emergency*," the right of a community, "[u]pon the principle of self-defense, of *paramount necessity*, . . . to protect itself against an *epidemic of disease* which threatens the safety of its members," and "the power of the public to guard itself against *imminent*

84. See Gerber, *supra* note 9, at 496 (noting that most childhood mandated vaccines protect against communicable diseases, but that some states require proof of immunization against hepatitis B which can be transmitted via sexual contact). Some states mandate that children be vaccinated against Hepatitis B as a prerequisite for school admittance. "Like HPV, hepatitis B vaccine targets viruses that are transmitted from person to person, mostly through sexual contact (although HBV also is commonly transmitted by exchange of blood products (e.g., sharing 'dirty needles'))." However, an "analogy between HBV and HPV is imperfect for policy decisions." Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 VACCINE 4812, 4814–15 (2006).

85. Hendricks, *supra* note 78.

*danger.*⁸⁶ For the past century, cases upholding mandatory vaccination laws in accordance with *Jacobson* have one common feature: “the vaccine in question targeted a disease that could easily be transmitted to all members of the community.”⁸⁷ As such, only state-mandated vaccination laws directed at highly contagious diseases affecting all segments of the population may be legally compelled.⁸⁸ Though HPV and cervical cancer are serious diseases with which the public should be concerned, HPV simply does not present the imminent danger smallpox presented in *Jacobson*. Additionally, because HPV is not spread via casual contact, it does not pose a threat to all segments of the population.

HPV is not highly contagious and even without the vaccine, cervical cancer would remain relatively rare.⁸⁹ For this reason, some in the medical community have questioned the ethics of mandating the vaccine. As one doctor stated, “[b]ecause HPV is not spread through the germ incubator of the classroom, a mandatory vaccine would lack that rationale.”⁹⁰ Therefore, “[u]nlike vaccinations for mumps or tetanus, diseases which can make it dangerous for children to even attend school together, the case for mandatory HPV vaccinations requires closer scrutiny.”⁹¹ This alone has led many to determine that the HPV vaccine should not be mandated as a prerequisite for school admittance:

“HPV is not caught by sitting next to someone in class but by sexual contact, which often is a lifestyle choice Using school laws, which were developed to protect children from communicable diseases like smallpox and measles, to mandate vaccination against a sexually transmitted infection, is to use the ends to justify the means.”⁹²

2. The HPV Vaccine Is Not “Essential,” as Required by *Jacobson*

Mandating HPV vaccination also reaches beyond the confines of *Jacobson* because the vaccine is not “essential” to protect the public from the health threat of HPV and cervical cancer. Although the Court

86. *Jacobson v. Massachusetts*, 197 U.S. 11, 27–29 (1905) (emphasis added).

87. Carrie A. Roll, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*, 10 J. HEALTH CARE L. & POL’Y 421, 431 (2007).

88. See Sanzo, *supra* note 31, at 35 (“[V]accines directed at highly contagious diseases affecting all members of the population may be made compulsory. In contrast, a vaccine directed against a disease such as AIDS may not be legally compelled because the vast majority of the population is not at risk for the disease.”).

89. Gerber, *supra* note 9, at 496.

90. Hendricks, *supra* note 78 (quoting Dr. Richard Zimmerman).

91. Gerber, *supra* note 9, at 496.

92. Hendricks, *supra* note 78 (quoting Dr. Richard Zimmerman).

explained that the Constitution does not “import an absolute right in each person to be . . . wholly freed from restraint,”⁹³ it also stressed that this restraint is limited to situations necessary “to secure the general comfort, health, and prosperity of the state.”⁹⁴ As the Court noted: “The possession and enjoyment of all rights are subject to such *reasonable* conditions as may be deemed by the governing authority of the country *essential* to the safety, health, peace, good order, and morals of the community.”⁹⁵ HPV simply does not fit into this narrow category.

Mandating the HPV vaccine is not “essential” to the safety and health of the community for two reasons. First, the vaccine is not essential to protect communities against the threat of HPV because there are other means to prevent or reduce the risk of HPV infection. At one extreme, abstinence, for obvious reasons, provides a better preventative option than the vaccine because it is the only certain method that will prevent HPV infection. And, for those who are sexually active, other preventative methods can reduce the risk of infection. Condom use, for example, reduces the risk of contracting HPV⁹⁶ and, as between condom use and the HPV vaccine, condom use is arguably more effective because it can reduce the risk of contracting all strains of HPV, while the vaccine only prevents infection against four of the forty HPV strains. Monogamy with an uninfected partner is also a viable preventative alternative.⁹⁷ Because other methods of prevention and protection against HPV exist, it is difficult for states to meet the heavy burden of showing that the vaccine is “essential” to protect the public health.

Second, the HPV vaccine is not essential to protect women against the health threat of cervical cancer because “[t]he majority of cervical cancer cases and deaths can be prevented through detection of pre-cancerous changes in the cervix by cytology using the Pap test.”⁹⁸ Moreover, because the vaccine only protects against two of the HPV strains that cause cervical cancer, it will not eliminate the need for cervical cancer screening.⁹⁹ Also, the future effectiveness of the vaccine to protect against cervical cancer is uncertain, whereas the Pap test has provided consistent and effective results for decades. For example, while

93. *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905).

94. *Id.* (quoting *Hannibal & St. J. R. Co. v. Husen*, 95 U.S. 465, 471 (1877)).

95. *Id.* (quoting *Crowley v. Christensen*, 137 U.S. 86, 89 (1889) (emphasis added)).

96. *MMWR*, *supra* note 14, at 7.

97. *Id.*

98. *Id.*

99. *Id.*

the vaccine is effective against the two strains of HPV that cause 70% of cervical cancers, this statistic is misleading because it “looks at the women who are being diagnosed with cervical cancer today. These women contracted HPV 15 to 20 years ago. In other words, Gardasil[®] is very effective against the cancer-causing vaccine strains that were prevalent 15 to 20 years ago[.]”¹⁰⁰ However, we cannot be certain that Gardasil[®] will remain as effective in the future.

B. State-Compelled HPV Vaccination Laws Violate the Constitution

In *Jacobson*, the Supreme Court specified that a state’s right to use reasonable means to protect the public health may not “contravene the Constitution of the United States or infringe any right granted or secured by [the Constitution].”¹⁰¹ State laws mandating that girls receive HPV vaccination as a prerequisite for school admittance are in contravention of the Constitution. These mandates are unconstitutional because they violate the Fourteenth Amendment in two ways. First, they violate due process by infringing on parents’ constitutional right to regulate their children’s sexual behavior as they see fit—a right that is within the confines of the freedom of choice in family life, which is secured by the Due Process Clause. Second, these mandates are unconstitutional because they violate equal protection by mandating the vaccine to women, members of a protected class, but not to men.

1. Due Process Violations

A three-step inquiry is appropriate when evaluating whether a state mandated policy violates due process: (1) Does the policy intrude on a constitutionally protected right?; (2) If so, is there a compelling state interest to do so?; and finally, (3) Is the policy in question absolutely necessary to meet that compelling state interest? Application of this analysis to state-mandated HPV vaccination laws readily establishes that such laws violate the Due Process Clause of the Fourteenth Amendment.

First, mandating the HPV vaccine as a prerequisite for public and private school admittance intrudes on a constitutionally protected right. Broadly speaking, the child-parent relationship and the freedom of personal choice in family-related matters are constitutionally protected

100. Onder, *supra* note 81.

101. *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

under the Due Process Clause.¹⁰² More specifically, parents have a constitutionally protected right to regulate their children's sexual behavior as they see fit.¹⁰³ Mandating the HPV vaccine intrudes on this constitutional right. The parents' decision of how to best protect their children against the risk of HPV is a constitutionally protected decision because the HPV infection, unlike other diseases and infections for which states compel vaccination, is directly linked to the child's sexual behavior. State laws mandating the HPV vaccine, therefore, intrude on this constitutionally protected parental right. The American College of Pediatricians agrees: "Families with firmly enforced restrictions on sexual conduct, whose children do not participate in penetrating vaginal sexual intercourse outside of marriage, should have those values respected; it should be acknowledged that the child will not require HPV vaccination prior to marriage."¹⁰⁴ Similarly, families whose children are sexually active or may one day become sexually active prior to marriage should be allowed to decide how best to protect their children from the risks associated with sexual behavior because, as previously mentioned, the HPV vaccine is not the only way to protect against HPV and cervical cancer. Accordingly, mandating HPV vaccination infringes on the parents' constitutional right to regulate their children's sexual behavior as they see fit because it destroys the parents' freedom of choice by replacing the decisionmaking of the parent with that of the state government.

Second, although mandating HPV vaccination intrudes on parents' constitutionally protected right, is there a compelling state interest to do so? The public health as a whole is a compelling state interest. As evidence, when the Supreme Court confirmed that the authority to impose mandatory vaccination fell within the confines of a state's police power in *Jacobson*, it did so under the rationale that "the 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."¹⁰⁵ Because HPV is a public health concern,¹⁰⁶ there is a state interest in mandating a vaccine that would

102. *Quilloin v. Walcott*, 434 U.S. 246, 255 (1977).

103. *Alfonso v. Fernandez*, 606 N.Y.S.2d 259, 265 (N.Y. App. Div. 1993).

104. Gerber, *supra* note 9, at 496 (quoting Susan Weisbergh & David Castellan, *Human Papilloma Virus Vaccination*, American College of Pediatricians Web site, Jan. 12, 2007, <http://acpeds.org?CONTEXT=art&cat=10006&art=140&BISKIT=1544652239>). *See also* Hendricks, *supra* note 78 ("Some say a compulsory vaccination would tread on the value of abstinence before marriage that they instill in their children.").

105. *Jacobson*, 197 U.S. at 25.

106. *HPV Vaccine: HPV Vaccine Legislation*, *supra* note 3 (noting that "HPV infects

prevent the spread of the disease and, ultimately, cervical cancer. However, because HPV is not spread via casual contact, does not affect all segments of the population, and is not the only method of prevention, this state interest is likely not “compelling.”

Even assuming that, though state-mandated HPV vaccination laws intrude on a constitutionally protected right, there is a *compelling* state interest to do so, we must consider whether mandatory HPV vaccination as a prerequisite for school admittance is absolutely necessary to meet the state’s compelling interest in protecting its residents from the health threats of HPV and cervical cancer. It is here that the due process violation becomes most apparent—the HPV vaccine is not absolutely necessary to serve this state interest because there are other methods of preventing HPV and cervical cancer, some of which are more effective than the HPV vaccine.

Application of this three-step inquiry readily establishes that state-mandated HPV vaccination laws violate due process; however, a look to case law is also instructive. In *Alfonso v. Fernandez*,¹⁰⁷ application of this three-step analysis lead the court to conclude that a state-compelled condom distribution program violated the parents’ constitutional right to due process.¹⁰⁸ The condom distribution program at issue in *Alfonso* was developed out of an HIV and AIDS Education Program established in New York City’s public high schools.¹⁰⁹ The program consisted of two components: first, the Educational Component, which was designed to educate the students on the means of infection and methods of preventing HIV and AIDS;¹¹⁰ second, the Condom Distribution Component, which was designed to ensure condoms were readily available to students upon request.¹¹¹ The court did not find the Educational Component, alone, to be in violation of any constitutional right. As the court noted, had the parents complained “solely about having their children exposed to ideas or a point of view with which they disagree[d] or [found] offensive . . .

approximately 20 million people in the United States with 6.2 million new cases each year” and that “[t]here are more than 30 strains of HPV that affect at least half of sexually active people in their lifetime”).

107. 606 N.Y.S.2d 259 (N.Y. App. Div. 1993).

108. *Id.* at 268. *But see* *Curtis v. Sch. Comm. of Falmouth*, 652 N.E.2d 580, 586 (Mass. 1995) (declining to apply *Alfonso* to a similar condom-distribution program because “[a]lthough exposure to condom vending machines and to the program itself may offend the moral and religious sensibilities of the plaintiffs, mere exposure to programs offered at school does not amount to unconstitutional interference with parental liberties without the existence of some compulsory aspect to the program”).

109. *Alfonso*, 606 N.Y.S.2d at 261–62.

110. *Id.* at 261.

111. *Id.*

such opposition would falter in the face of the public school's role in preparing students for participation in a world replete with complex and controversial issues."¹¹² However, the court found the Condom Distribution Component problematic because "[s]tudents [were] not just exposed to talk or literature on the subject of sexual behavior" but instead, "the school [offered] the means for students to engage in sexual activity at a lower risk of pregnancy and contracting sexually transmitted diseases."¹¹³ While the court acknowledged that the crux of the Condom Distribution Component was to prevent the spread of HIV and AIDS and not to encourage an increase in sexual activity amongst students, it concluded that "[n]o matter how laudable its purpose, by excluding parent involvement, . . . [the Condom Distribution Component] impermissibly trespassed on . . . parental rights by substituting the [school] in loco parentis, without a *compelling* necessity therefore."¹¹⁴

As in *Alfonso*, many opposed to mandating the HPV vaccine fear it may lead young girls, under the mistaken belief the vaccine protects against all strains of HPV or even other sexually transmitted infections, to engage in risky sexual behaviors they would otherwise avoid.¹¹⁵ Yet the present concern is even more alarming than that in *Alfonso* when one considers that engaging in risky sexual behavior while using a condom is substantially less dangerous than engaging in the same behavior under the mistaken belief that the HPV vaccine provides similar protection. Regardless of the degree of danger involved or reality of such concerns, the crux of these considerations is that their import will differ from family to family, parent to parent. A state's desire to prevent HPV and, ultimately, cervical cancer is commendable; yet, "[n]o matter how laudable [their] purpose,"¹¹⁶ state-mandated HPV vaccination laws violate parents' constitutional right to regulate their children's sexual behavior as they see fit by removing the parent from the decision making process. The ends simply do not justify the means.

112. *Id.* at 266.

113. *Id.*

114. *Id.* at 265 (emphasis added).

115. See Hendricks, *supra* note 78 (noting that critics of vaccine mandates "fear that the vaccine might encourage promiscuity if youth view the vaccine as a talisman against all sexually transmitted diseases"); Zimmerman, *supra* note 84, at 4814 (noting the concern "that some vaccinees may mistakenly assume that HPV vaccine protects against other STIs").

116. *Alfonso*, 606 N.Y.S.2d at 265.

2. Equal Protection Violations

As previously stated, arguments that mandatory vaccination laws violate equal protection have failed in the past on the grounds that such laws treat all schoolchildren equally. However, while laws mandating vaccination of schoolchildren do not violate equal protection in and of themselves, the same cannot be said if, when applied, those same laws in fact discriminate against members of a protected class.¹¹⁷ For this reason, laws mandating that young girls receive the HPV vaccine as a prerequisite for public and private school admittance are also in contravention of the Constitution because they violate the Equal Protection Clause of the Fourteenth Amendment by discriminating against females—members of a protected class based on gender.

Because Virginia is currently the only state that has enacted a mandatory HPV vaccination law, we will analyze its statute subject to intermediate scrutiny for equal protection violations. The sex-based classification in the Virginia statute is in violation of the Equal Protection Clause, unless the following elements are established: (1) the sex-based classification serves an important governmental objective; and (2) the discriminatory means employed in the statute are substantially related to achieving that important governmental objective.¹¹⁸

The relevant portion of the Virginia statute provides:

The required immunizations for attendance at a public or private . . . school . . . shall be those set forth in the State Board of Health Regulations for the Immunization of School Children. The Board's regulations shall at a minimum require . . . [t]hree doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade.¹¹⁹

To determine whether this statute violates the Equal Protection Clause, we must first determine whether the sex-based classification contained in the statute serves an important governmental objective. A state has an interest in protecting the health and safety of its citizens. Mandating that young women receive the HPV vaccine, therefore, serves Virginia's important governmental objective of protecting its citizens from HPV, a disease which is clearly a public health concern.

117. Hodge & Gostin, *supra* note 30, at 862.

118. See *supra* notes 67–71 and accompanying text.

119. VA. CODE. ANN. § 32.1-46(A)(12) (2007) (effective Oct. 1, 2008).

Determining that an important governmental objective is served by this sex-based classification, namely, the prevention of HPV, we now turn to the question of whether the discriminatory means employed are substantially related to the achievement of this objective. Herein lies the problem: the requisite substantial relationship between the governmental objective and the discriminatory means is not met.

Although the HPV vaccine was developed to prevent cervical cancer,¹²⁰ a disease unique to women, the vaccine *itself* does not prevent cervical cancer. Instead, it “targets the types of HPV that most commonly cause cervical cancer and genital warts.”¹²¹ In line with the actual purpose of the vaccine, the Virginia statute explicitly speaks to HPV—not cervical cancer.¹²² Because HPV affects both men and women,¹²³ the most glaring error in any argument that the vaccine is *substantially* related to the state’s objective of preventing HPV is that the means are designed to protect only roughly half of the population affected by the disease. Moreover, of that subset, the vaccine protects an even smaller percentage because it is ineffective against certain types of HPV and is ineffective in those already exposed to the four strains of HPV the vaccine is designed to prevent.¹²⁴ Thus, because the vaccine protects less than half of the population affected by HPV, it cannot be said that mandating young women be vaccinated as a prerequisite for public and private school admittance is substantially related to the state’s objective.

One could argue these discriminatory means are justified because the vaccine currently is only approved for use by women. However, this is merely because the vaccine was only tested on women before it was approved by the FDA; it has not yet been shown that the vaccine is not safe for use by men.¹²⁵ In fact, “[s]tudies are now being done to find out if the vaccine is also safe in men, and if it can protect them against genital warts and certain penile and anal cancers.”¹²⁶ Thus, this

120. FDA Licenses New Vaccine, *supra* note 1.

121. Vaccines: Safety and Efficacy Q&A, *supra* note 11.

122. VA. CODE. ANN. § 32.1-46(A)(12). Although the statute mentions cervical cancer, this is limited to the opt-out provision of the statute and merely speaks to the link between HPV and cervical cancer. In fact, the opt-out provision is in place specifically “[b]ecause the human papillomavirus is not communicable in a school setting.” § 32.1-46(D)(3).

123. See CDC Recommends HPV Vaccination, *supra* note 2 (“HPV is the most common sexually transmitted infection in the United States, More than 20 million *men and women* in the United States are currently infected with HPV” (emphasis added)).

124. Vaccines: Safety and Efficacy Q&A, *supra* note 11.

125. *Id.*

126. CENTERS FOR DISEASE CONTROL AND PREVENTION, HPV AND MEN 2 (2007), <http://www.cdc.gov/std/hpv/HPV&Men-Fact-Sheet.pdf>.

argument fails and actually serves as support for the concern of many opponents of the mandates that because “the long-term effects and efficacy of the vaccine are unknown . . . [i]n a regime of mandatory HPV vaccination for girls, unintended side effects could have vast public health implications.”¹²⁷

In sum, protecting citizens from HPV is an important governmental objective and Virginia’s statute mandating the HPV vaccine, though discriminatory, does serve this objective. However, any justification for the sex-based discrimination in the statute is not exceedingly persuasive because the discriminatory means are not substantially related to the achievement of that governmental objective. Therefore, Virginia’s statute violates the Equal Protection Clause of the Fourteenth Amendment and, for these same reasons, any other strict state mandate of HPV vaccination directed only at girls would violate the Equal Protection Clause.

3. Exemptions Do Not Solve the Constitutional Issues

All states offer medical exemptions from compulsory vaccination and many also offer religious and philosophical exemptions. However, the mandatory vaccination law upheld by the Supreme Court in *Jacobson* contained only a medical exemption.¹²⁸ As such, the case merely furnishes constitutional support for medical exemptions from state-mandated vaccination laws.¹²⁹ Exemptions from the HPV vaccine based on either a religious or philosophical rationale present constitutional problems and even overall health concerns because of their effect on the very goal of mandating the vaccine—eradicating HPV. Allowing these exemptions will not solve the constitutional issues inherent with strict state mandates of the HPV vaccine as a prerequisite for school admittance.

Because strict HPV vaccination mandates extend beyond the power granted by the Court in *Jacobson* and are in contravention of the Constitution, one might assume that the natural solution is to provide exemptions from the mandate in the state statutes. In fact the governor of Virginia, in response to pressure from opponents of the state’s strict

127. Gerber, *supra* note 9, at 496.

128. *Jacobson v. Massachusetts*, 197 U.S. 11, 12 (1905). Specifically, the statute provided that “children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination” were exempt. *Id.*

129. Linda E. LeFever, Comment, *Religious Exemptions from School Immunization: A Sincere Belief or a Legal Loophole?*, 110 PENN ST. L. REV. 1047, 1058 (2006).

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HPV vaccine mandate, sent the bill back to incorporate an opt-out provision before signing the bill into law.¹³⁰ However, religious and philosophical exemptions from the vaccine are as equally contentious as strict mandates of the vaccine. The constitutional problems with these two exemptions are considered next, as well as the concern that these exemptions threaten herd immunity, making the purpose behind the vaccination laws themselves moot.

a. Religious Exemptions

To date, the Supreme Court has yet to address the constitutionality of religious exemptions to state-compelled vaccination laws.¹³¹ However, such exemptions are likely unconstitutional because they violate the Fourteenth and First Amendments.

i. Equal Protection Concerns

Religious exemptions may violate equal protection two ways. First, “they discriminate against people who have unrecognized or unestablished religious beliefs against vaccination.”¹³² Second, they discriminate against people “who have received vaccinations yet remain vulnerable to the diseases for which they [have] been vaccinated.”¹³³

There are two categories of religious exemptions from mandatory vaccination laws. First, some states require that the religion is an organized religion or at least that the person requesting a religious exemption have a sincere religious belief.¹³⁴ The second type of religious exemption, employed by the majority of the states, “simply require[s] applicants to submit a form stating that they oppose vaccination on religious grounds.”¹³⁵ The first type of religious exemption violates “the Equal Protection Clause by giving preferential treatment to certain groups while ignoring others who have sincere, though unrecognized, religious objections.”¹³⁶

130. Gerber, *supra* note 9, at 495.

131. Alicia Novak, *The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges*, 7 U. PA. J. CONST. L. 1101, 1107 (2005).

132. *Id.* at 1115.

133. *Id.* at 1116.

134. *Id.* at 1107–08.

135. *Id.* at 1108.

136. *Id.* at 1115.

While it may be easier to see the equal protection violation inherent in the first type of religious exemption, the second type is equally problematic. Allowing a child exemption from a vaccine mandate because they oppose the vaccination on religious grounds is unconstitutional under the Equal Protection Clause because it “discriminate[s] against the great majority of children whose parents have no such religious convictions.”¹³⁷ Though the latter type of religious exemption is less concerning, insofar as equal protection is concerned, because it allows more children to claim a religious exemption, the two categories of religious exemptions are really two sides of the same coin because both effectively discriminate against some *subset* of those who do not adhere to “established” religions. These problems will become even more apparent if religious exemptions are allowed from state mandates of the HPV vaccine because of the inherent religious undertones presented by a vaccine designed to prevent a sexually transmitted infection.

ii. First Amendment Concerns

Religious exemptions from vaccination laws also violate the First Amendment of the Constitution. The Religious Clause of the First Amendment, which is made up of the Establishment Clause and the Free Exercise Clause respectively, provides that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof.”¹³⁸ Because the Establishment and Free Exercise Clauses are “frequently in tension,” a law “must be ‘permitted by the Establishment Clause, but not required by the Free Exercise Clause’” to strike the proper balance between religion and government.¹³⁹ Religious exemptions from state-mandated vaccination are not required under the Free Exercise Clause; however, such exemptions might be impermissible under the Establishment Clause.¹⁴⁰ As the Supreme Court stated, “[t]he 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 death.”¹⁴¹ Thus, we must examine the effect of religious exemptions

137. *Id.* at 1116 (quoting *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979)).

138. U.S. CONST. amend. I.

139. *LeFever*, *supra* note 129, at 1059 (quoting *Lock v. Davey*, 540 U.S. 712, 719 (2004)).

140. *See id.* at 1062 (“[I]t is possible that such an exemption may not be a permissible accommodation under the Establishment Clause.”)

141. *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944).

from state-compelled vaccination laws against vaccinated children as well as children that remain unvaccinated due to a religious exemption.

In *Lemon v. Kurtzman*,¹⁴² the Supreme Court established a three-part test to determine whether a statute is permissible under the Establishment Clause. “The *Lemon* test requires 1) that the statute have [sic] a secular legislative purpose; 2) that its principal or primary effect does not advance or inhibit religion; and 3) that the statute does not impermissibly entangle government and religion.”¹⁴³ Thus, exemptions that apply only to “recognized religions,” for example, violate the second and third prongs of the *Lemon* test.¹⁴⁴ As such, many states have abandoned exemptions that apply only to “recognized religions” in favor of exemptions that apply to those with sincerely held religious beliefs.¹⁴⁵ However, an argument can be made that even these exemptions violate the second prong of *Lemon*:

While the government is not directly furthering religion by providing a religious exemption to an immunization law, it is possible that such an exemption may not be a permissible *accommodation* under the Establishment Clause. In recognizing a religious exemption, states eliminate the burden immunization laws impose on an individual's religious beliefs. However, in absolving these individuals from immunization requirements, the burden to protect the community from disease shifts solely to the non-religious. When viewed in this context, it is clear that states providing a religious exemption are conferring a benefit to the religious that is not extended to the non-religious. Considering the dangers associated with a decision not to vaccinate a child, an exempted child does not appear to acquire a benefit. However, as long as a substantial number of other children in the community are vaccinated, exempted children benefit from the immunity of their peers. Additionally, unvaccinated children are able to avoid the discomfort and possible adverse event[s] associated with vaccination.¹⁴⁶

Justice O'Connor, in the following oft-cited quote, lends further support to this argument, stating that the Establishment Clause and Free Exercise Clause, among others, “all speak with one voice on [religion]: Absent the most unusual circumstances, one's religion ought not affect one's legal rights or duties or benefits.”¹⁴⁷ Though this speaks

142. 403 U.S. 602 (1971).

143. LeFever, *supra* note 129, at 1061 (citing *Lemon v. Kurtzman*, 403 U.S. at 612–13).

144. *Id.* at 1062.

145. *Id.*

146. *Id.* at 1062–63 (emphasis added).

147. Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet, 512 U.S. 687, 715 (1994)

specifically to one's own religious benefits, the same principle should carry over so that one's religion ought not affect *another's* legal benefits. Moreover, the latter is arguably a more precious right to protect because one's legal rights, duties, and benefits should not be affected by the actions of others over whom she has no control.

Religious exemptions may infringe on the exempted child's First Amendment rights as well. In *Prince v. Massachusetts*,¹⁴⁸ the Supreme Court stated that "[p]arents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."¹⁴⁹ Though the proposition that religious exemptions infringe on the First Amendment rights of the exempt may seem contradictory at first glance, one must consider the following question before jumping to such conclusions: how often will the *child herself* oppose mandatory HPV vaccination based on her own religious beliefs? More often, it will be the parent who opposes the child's vaccination based on the parent's own religious beliefs. Thus, in consideration of this proposition, "the power of the parent, even when linked to a free exercise claim, may be subject to limitation under *Prince* if it appears that parental decisions will jeopardize the health or safety of the child."¹⁵⁰

Recognizing this contradiction, the Mississippi Supreme Court found its religious exemption unconstitutional.¹⁵¹

Harkening back to the "martyr" language of *Prince v. Massachusetts*, the court asked, "Is it mandated by the First Amendment to the United States Constitution that innocent children, too young to decide for themselves, are to be denied the protection against crippling and death that immunization provides because of a religious belief adhered to by a parent or parents?"¹⁵²

As with equal protection, these First Amendment issues will become more apparent in light of a religious exemption from the HPV vaccine because decisions related to future sexual behaviors are beyond the full comprehension of a child.

(O'Connor, J., concurring).

148. 321 U.S. 158 (1944).

149. *Id.* at 170.

150. *Wisconsin v. Yoder*, 406 U.S. 205, 233–34 (1972).

151. Silverman, *supra* note 76, at 283 (discussing *Brown v. Stone*, 378 So. 2d 218, 224 (Miss. 1979)).

152. *Id.* (quoting *Brown v. Stone*, 378 So. 2d at 221).

b. Philosophical Exemptions

The philosophical exemption also lacks constitutional support.¹⁵³ One may argue that philosophical exemptions at least do away with some of the equal protection concerns inherent in religious exemptions because philosophical exemptions do not discriminate against those with unrecognized or unestablished religious beliefs. Yet, in exchange for this freedom philosophical exemptions pay a high price by compromising the public health at large. In states that have both religious and philosophical exemptions, statistics show that the vast majority of those claiming exemption do so under the philosophical exemption.¹⁵⁴ Thus, because they provide for an even lower burden of proof, philosophical exemptions are arguably more problematic because they cause a greater number of children to claim exemption, which, in turn, leaves fewer children immunized.¹⁵⁵

c. Public Health Concerns

All types of exemptions from state-compelled vaccination laws pose a threat because they undermine the very thing such mandates were designed to protect—the public health. When a sufficient percentage of a community is immunized, those who are not vaccinated can still benefit from the protection of those members who are vaccinated.¹⁵⁶ This concept is known as “herd immunity.”¹⁵⁷ However, as exemption rates continue to increase, “immunization rates fall below [the] critical threshold” and the herd immunity is compromised.¹⁵⁸ “Therefore, society cannot allow every one of its members (or even a sizeable minority) to rely on the indirect protection afforded by other vaccinated members of the herd—because then community protection unravels as all try to ‘free ride’ off of the benevolent acts of others.”¹⁵⁹

This concern is even greater with exemptions from the HPV vaccine. Traditional vaccines that have been around for many decades were able

153. LeFever, *supra* note 129, at 1065.

154. See Calandrillo, *supra* note 75, at 433 (stating that “[i]n Washington, up to 95% of all exemptions were claimed for personal, not religious, reasons. Data from Colorado show a similar pattern, as parents who opted out of vaccination were 10 times more likely to choose philosophical reasons than religious ones”).

155. Novak, *supra* note 131, at 1108, 1110.

156. Calandrillo, *supra* note 75, at 420.

157. *Id.*

158. *Id.* at 419.

159. *Id.* at 420.

to establish a strong foundation of herd immunity. For example, the eradication of diseases like smallpox and polio in this country is largely attributable to the fact that exemptions from vaccination against these diseases did not exist until after the population at large was subjected to strict vaccination mandates for a long span of time. Exemptions from the HPV vaccine, however, would come concurrently with the mandates themselves, leaving a slim possibility of ever establishing herd immunity from HPV.

Exemptions from the HPV vaccine also carry an extremely high risk of creating cluster problems. “A cluster problem occurs when those who apply for the exemptions live in clusters in close proximity to one another.”¹⁶⁰ The cluster problem is a very real concern with religious exemptions because clusters may form around churches or in certain religious communities.¹⁶¹ For instance, “[r]eligious exemptions to vaccination in Amish, Mennonite and Christian Science communities are responsible for the last two major outbreaks of polio in America” and “[i]n 1991, lack of widespread immunizations in Amish areas resulted in 890 cases of rubella.”¹⁶² “Recent studies have shown that clusters of exemptors, who are significantly more susceptible to contracting vaccine preventable illnesses, pose an increased risk of spread of disease not only to their unimmunized peers, but also to the surrounding, largely vaccinated population.”¹⁶³ Because large numbers of the religious community are likely to oppose vaccination against a sexually transmitted infection, the threat of creating a cluster problem is increased with exemptions from the HPV vaccine.

These problems illustrate the paradox created by exemptions from state-compelled HPV vaccination laws. Strict mandates are unconstitutional and while exemptions might temper their unconstitutional effect, swinging the pendulum back so that HPV vaccination laws with exemptions seemingly have legal footing, these exemptions ultimately work to destroy the protection HPV vaccination laws are designed to provide and, moreover, the exemptions themselves may be unconstitutional. Once the foundation for an HPV vaccination mandate is lost—to protect the public health—there is even less of a rationale to establish a mandate in the first place, particularly in light of the standards set forth by the Court in *Jacobson*.

160. Novak, *supra* note 131, at 1122.

161. *Id.* at 1123.

162. Calandrillo, *supra* note 75, at 422–23.

163. Novak, *supra* note 131, at 1123 (quoting Silverman, *supra* note 75, at 285).

C. *How States Should Handle the Health Threat of HPV and Cervical Cancer and the HPV Vaccine*

Because state laws mandating girls receive HPV vaccination as a prerequisite for school admittance overstep the authority granted by the Supreme Court in *Jacobson* and are in derogation of the Constitution, states should not enact such laws, even with exemptions. Instead, states should enact legislation aimed at the goal of educating their citizens about HPV and its relationship to cervical cancer so that families are able to make an informed decision as to whether the HPV vaccine is the right preventative method for their daughters.

The power of education in relation to the decision of whether to vaccinate girls against HPV was demonstrated during the First Annual Cervical Cancer/HPV Conference when conference attendees were asked whether they would support laws mandating the vaccine for girls as a prerequisite for entering middle school.¹⁶⁴ At the beginning of the conference, only a minority of the attendees voted in favor of such mandates.¹⁶⁵ However, after the attendees listened to a presentation regarding the pertinent information and facts about the HPV vaccine, more than 70% favored a mandate after a second vote.¹⁶⁶

An educational and informational approach is the one approach that can effectively compromise between both sides of the debate. In response to the HPV vaccination mandate considered in the District of Columbia, two D.C. residents, both mothers of young girls in the D.C. school district, expressed polar views. One mother felt that mandate violated her rights: "I don't think the government has a right to tell us that we should vaccinate our kids against [sexual] behavior It's more important to educate girls about that behavior as opposed to giving them a drug that may even exacerbate it."¹⁶⁷ Conversely, the other mother said: "Preventing a disease that we know we [have the ability to] prevent that leads to death, that's a no-brainer for me."¹⁶⁸ An educational approach is amenable to the former side of the debate, because it puts the decision-making power in the parents' hands while

164. *Cancer Vaccines: The First Annual Cervical Cancer/HPV Conference Tackles Controversial Vaccine Issues and Encourages Advocacy*, WOMEN'S HEALTH WEEKLY, Oct. 11 2007, at 48.

165. *Id.*

166. *Id.* Those who voted in favor of mandates the second time did so, only provided that the mandates contained an exemption provision. *Id.*

167. Adrienne T. Washington, *Make Informed Decision About HPV Vaccine*, WASH. TIMES, Sept. 25, 2007, at B2.

168. *Id.*

ensuring that families and their daughters receive the information necessary to make a decision that will best suit their individual needs. And this approach is amenable to the latter side of the debate because parents with strong feelings in favor of the vaccine likely do not need motivation in the form of a state mandate to make the decision to vaccinate their daughters.

In 2007, Indiana lawmakers chose to take an informational and educational approach, agreeing that providing parents with information rather than mandating HPV vaccination would not “intrude on parental rights.”¹⁶⁹ The Indiana statute provides that any school enrolling sixth-grade girls “shall provide each parent of a female student who is entering grade 6 with information . . . concerning the link between cervical cancer and the human papillomavirus (HPV) infection and that an immunization against the human papillomavirus (HPV) infection is available.”¹⁷⁰

Pursuant to this statute, the Indiana State Department of Health created a letter and “fact sheet” to send parents. It prepared this information with the goal that the materials would provide information about HPV and the HPV vaccine in an easy to understand manner. To achieve this goal, the Department presented the information at an eighth-grade reading level.¹⁷¹ The Department’s efforts resulted in a letter and accompanying two-page fact sheet that were reviewed four times by a group of fifty experts, including school nurses and pediatricians, and revised accordingly.¹⁷² The fact sheet sent at the beginning of the 2007–

169. Zach Spicer, *HPV Notes Going Home: Schools Report Good Response to Information*, THE TRIB. (Jackson County, Indiana), Sept. 5, 2007, at 1A.

170. Ind. Code § 20-34-4-3(b) (2007). The statute further provides:

(c) The state department of health shall provide a school described in subsection (b) with the information concerning the cervical cancer and the human papillomavirus (HPV) infection required in subsection (b). The information must include the following:

(1) The latest scientific information on the immunization against the human papillomavirus (HPV) infection and the immunization’s effectiveness against causes of cervical cancer.

(2) That a pap smear is still critical for the detection of precancerous changes in the cervix to allow for treatment before cervical cancer develops.

(3) Information concerning the means in which the human papillomavirus (HPV) infection is contracted.

(4) A statement that any questions or concerns concerning immunizing the child against human papillomavirus (HPV) could be answered by contacting a health care provider.

Id. § 20-34-4-3(c).

171. Bryan Corbin, *Parents Get Word on HPV—Letter Explains Vaccine Options*, EVANSVILLE COURIER & PRESS (Indiana), Aug. 19, 2007, at A1.

172. *Id.*

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2008 school year provided information about HPV infection and the HPV vaccine.¹⁷³ The fact sheet explained the HPV virus and how it is contracted, that infection can be difficult to detect, and that the potential consequences of infection can be severe and untreatable. With regard to the vaccine, the fact sheet explained how the vaccine is administered, that the vaccine inoculates against several but not all types of HPV infection, and that inoculated women should still receive regular Pap tests to screen for cervical cancer. Although this fact sheet provides a workable framework, there is room for improvement.

It is imperative that the fact sheet conveys to parents why the vaccine is recommended for girls at such a young age. Although many parents are concerned with the social implications of vaccinating their daughters against an infection that is transmitted via sexual contact, the benefit of vaccination at a young age is to target girls before they become sexually active because as sexual partners increase, so does the probability that an individual will contract one of the HPV strains the vaccine is designed to prevent, thereby making vaccination ineffective.¹⁷⁴ In addition, the fact sheet should explicitly state that condom use, though effective at preventing HPV, is not 100% effective and that abstinence is the only certain method of preventing infection. The fact sheet should also explicitly make the connection that, because the vaccine only protects against these strains, other methods of protection are still critical for those who are sexually active to protect against the other HPV strains and other sexually transmitted infections and diseases.

After implementing these changes, the Indiana fact sheet provides a strong example of information other states should send to parents. However, in addition to the fact sheet, states should provide parents an opt-in to school-run programs that anonymously provide the vaccine to students. Such programs will not violate parents' constitutional rights and will provide a financially viable solution for those who choose to receive the HPV vaccine.

An opt-in school-run HPV vaccination program is constitutional because an opt-in program allowing students to receive the HPV vaccine anonymously is optional for the parents first and only then to the students of those parents that choose to opt-in. Moreover, if the Parental Right to

173. INDIANA STATE DEPARTMENT OF HEALTH, HUMAN PAPILLOMAVIRUS (HPV) FACT SHEET, <http://www.in.gov/isdh/programs/immunization/pdfs/HPVLetterandFactSheetEnglish.pdf>. The full text of the Indiana State Department of Health, Human Papillomavirus (HPV) Fact Sheet is reproduced at Appendix A.

174. George F. Sawaya & Karen Smith-McCune, *HPV Vaccination—More Answers, More Questions*, 356 NEW ENG. J. MED. 1191, 1192 (May 10, 2007).

Decide Act,¹⁷⁵ which “prohibit[s] Federal funding or other assistance for mandatory HPV vaccination programs,”¹⁷⁶ is passed into law, an opt-in program will provide a better financial alternative than state mandated HPV vaccination programs because federal money could be used to fund the vaccine for these programs.

It is a fact of life that many young girls are uncomfortable discussing sexually transmitted infections and their own sexual behaviors with their parents. “Without the ability to seek a vaccination independently, girls would probably rather risk an HPV infection”¹⁷⁷ For these reasons, the opt-in approach would allow parents to have informed conversations with their daughters about HPV, the HPV vaccine, and cervical cancer, but would ultimately provide a means of receiving the vaccine with some level of anonymity for those girls whose parents’ allow them to do so. This will likely increase the number of young girls who do receive the vaccine, which will have the overall effect of better protecting the public health at large.

V. CONCLUSION

There is no legal support for mandating HPV vaccination as a prerequisite for public and private school admittance. Strict mandates are problematic because they extend beyond the state’s power to compel vaccinations as established by the Supreme Court in *Jacobson v. Massachusetts* and because they are unconstitutional. Including exemptions from these mandates will not solve these initial problems created by strict mandates because the exemptions themselves may be unconstitutional and effectively work to destroy immunity. Therefore, states should not implement compulsory HPV vaccination laws.

However, this is not to say that states can not or should not pursue their interest in defending the public health of their citizens. Because the HPV vaccine is a preventative vaccine, it remains sensible to target the younger population as this group is less likely to be sexually active. However, HPV vaccination is not the only means of prevention and protection available and thus, an informational and educational approach is best. An opt-in school-run program provides a better option than an

175. Parental Right to Decide Protection Act, H.R. 1153, 110th Cong. (2007). Compare my opt-in school-run vaccination proposal to the condom distribution program in *Alfonso*, which was unconstitutional because, although it was optional for the students to get the condoms, the parents had no say.

176. *Id.*

177. Gerber, *supra* note 9, at 496.

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HPV vaccination mandate because it will educate the younger population instead of just giving them a shot. Education will arm students and their parents with the knowledge that, even if they get the vaccine, they still need to protect themselves from the other strains of HPV and that even vaccinated girls must continue to get annual Pap tests to prevent cervical cancer. This approach is the most effective means to protect the public health at large without overstepping the boundaries established in *Jacobson* or the Constitution.

VI. APPENDIX A: INDIANA STATE DEPARTMENT OF HEALTH, HUMAN PAPILLOMAVIRUS (HPV) FACT SHEET

Human Papillomavirus (HPV) Infection

HPV is a virus that causes many infections. HPV infection is one of the most common sexually transmitted diseases (STD). This infection is spread by skin-to-skin contact during sex with a person infected with HPV. It causes genital warts or infection to the cervix (the upper part of the vagina, which connects to the uterus or womb.)

The best way to prevent getting HPV is to not have sex, because a person usually can't tell if he or she is infected. Infected people can give the virus to others during sexual contact without knowing it. Most females get HPV soon after becoming sexually active.

Even though the HPV infection can go away on its own, it may last for months or years. There is no medication to treat HPV infection so it is very important to prevent infection or find its presence early.

HPV infection can cause cervical changes that can lead to cancer of the cervix. It can also cause cancer of other genital organs. A pap test, which examines the cells of the cervix, can find the presence of these cervical changes due to HPV infection. If the Pap test shows abnormal cells, a health care provider will do more tests and/or provide treatment as needed.

Human Papillomavirus (HPV) Vaccine

In June, 2006 the U.S. Food and Drug Administration (FDA) licensed a vaccine that can prevent HPV infection. It is to be used in girls and young women 9 to 26 years old. It is the first vaccine that can prevent cervical cancer.

There are over 100 different types of HPV virus. The vaccine only protects against four types of HPV. Two types (16 and 18) are known to cause 70% of cervical cancer. The other two types (types 6 and 11) can cause 90% of genital warts. The vaccine has been found to be 90–100% effective in preventing these four types of HPV infection. The vaccine does not treat girls or young women who are already infected with these four types of HPV or have genital warts.

The new vaccine is a series of three shots over six months. The vaccine is not made from live virus nor does it contain thimerosal or mercury. The vaccine is not licensed to give to boys and young men, although it is being tested in males.

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Because the vaccine prevents infection by these four types of HPV, it works best in girls and young women who have not been in contact with the HPV infection. The vaccine is licensed for girls/young women ages 9 to 26 years. The vaccine has been found to give better protection at the younger ages as compared to older ages. The Centers for Disease Prevention and Control (CDC) Advisory Committee on Immunization Practices recommends the HPV vaccine for all 11 and 12 year old girls and for those 9–26 who have not yet been vaccinated. Any concerns or questions should be discussed with a health care provider.

No one knows how long the vaccine will protect a recipient. Research has shown that there is at least a 5 year protection rate. The vaccine is not recommended for someone who is pregnant. The vaccine is not recommended for those who have something wrong with their immune system or certain other medical conditions. Major side effects are rare. The most common side effects are swelling or redness at the site of the shot and possibly fainting or nausea. These side effects are the same as with other vaccines.

The vaccine does not replace the need for cervical cancer screening through Pap tests. All girls and young women who have received the HPV vaccine and are sexually active, need regular Pap tests to find precancerous changes in the cervix and to have any precancerous changes treated before cervical cancer develops.