



Fall 9-1-2010

The Virginia Gardasil Law: A Constitutional Analysis of Mandated Protection for Schoolchildren Against the Human Papillomavirus

Christina O. Hud

Follow this and additional works at: <https://scholarlycommons.law.wlu.edu/crsj>



Part of the [Education Law Commons](#), [Fourteenth Amendment Commons](#), and the [Health Law and Policy Commons](#)

Recommended Citation

Christina O. Hud, *The Virginia Gardasil Law: A Constitutional Analysis of Mandated Protection for Schoolchildren Against the Human Papillomavirus*, 17 Wash. & Lee J. Civ. Rts. & Soc. Just. 223 (2010). Available at: <https://scholarlycommons.law.wlu.edu/crsj/vol17/iss1/12>

This Note is brought to you for free and open access by the Washington and Lee Journal of Civil Rights and Social Justice at Washington and Lee University School of Law Scholarly Commons. It has been accepted for inclusion in Washington and Lee Journal of Civil Rights and Social Justice by an authorized editor of Washington and Lee University School of Law Scholarly Commons. For more information, please contact christensena@wlu.edu.

The Virginia Gardasil Law: A Constitutional Analysis of Mandated Protection for Schoolchildren Against the Human Papillomavirus

Christina O. Hud *

Table of Contents

Introduction.....	224
I. The Impact of Injecting Gardasil into American Society.....	226
A. The Human Papillomavirus (HPV).....	226
B. The Gardasil Vaccine.....	229
II. Enforcing Gardasil Vaccinations in Public Schools: To What Extent Can the Government Constitutionally Require Schoolchildren to be Vaccinated with Gardasil?	231
A. Gardasil Vaccination is a Proper Use of Virginia’s Police Power Under the Tenth Amendment.....	231
B. Gardasil Vaccination Does Not Violate Substantive Due Process Through an Invasion of Bodily Privacy and Unwanted Bodily Intrusion	235
C. Exemptions from Mandated Vaccination and	

* Juris Doctor, Washington and Lee University School of Law 2011; Bachelor of Arts, *cum laude*, in Government and English Literature, Franklin and Marshall College 2008. Thank you to my Academic Advisors: Dean and Roy L. Steinheimer, Jr. Professor of Law Rodney A. Smolla, for his guidance and encouragement throughout this endeavor; and Professor Ann MacLean Massie for her acidic pen and helpful commentary. I would also like to thank The Honorable Joseph E. Irenas, S.U.S.D.J. for his continuous support throughout my law school career, and for being such a dedicated and inspirational figure of the legal profession. Sincerest thanks to Assistant U.S. Attorneys Matthew T. Smith and Jason M. Richardson for improving and refining my legal research and analytical skills, as well as for being superb teachers and exemplary role models. I also thank my mother, Dr. Oksana H. Baltarowich, for introducing me to the intersection of medicine and the law, assisting in the development of my research, and her steadfast encouragement. Finally, special thanks to the members of the 2010–11 Editorial Board for all their hard work in making this Volume a success.

Parental Rights	249
III. Gardasil: Selective or Equal Protection?.....	259
A. The Virginia Law As It Stands Violates the Equal Protection Clause.....	261
IV. Conclusion and Proposal to the Virginia General Assembly	264

Introduction

"We chose to help protect ourselves. Now the choice is yours."¹ This message of choice is the central marketing theme of Gardasil, the vaccine protecting against four harmful strains of the Human Papillomavirus (HPV).² But for girls entering the sixth grade in Virginia, the vaccine is not a choice, but rather is mandated as a prerequisite to their school attendance.³

Gardasil is a quadrivalent vaccine protecting against four HPV strains commonly linked to several genital and oral cancers, as well as to anogenital warts.⁴ Although many in the medical field regard it as a miracle drug,⁵ Gardasil has raised legal, social, and economic concerns

1. Learn About Gardasil, <http://www.gardasil.com/what-is-gardasil/cervical-cancer-vaccine/index.html> (last visited Feb. 22, 2010) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

2. *See id.* (providing information on Gardasil).

3. *See* Yamiche Alcindor, *Local Schools Urging Girls to Get HPV Vaccine*, WASH. POST, Aug. 21, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/08/20/AR2009082004186.html> (last visited Feb. 6, 2010) (discussing the Gardasil mandate in Virginia's public schools) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

4. *See* Learn About Gardasil, *supra* note 1 (describing Gardasil's chemical composition).

5. *See, e.g.*, Brenda Wilson, *States Consider Requiring HPV Vaccine for Girls*, NATIONAL PUBLIC RADIO, Feb. 5, 2007, at 1, <http://www.npr.org/templates/story/story.php?storyId=7190905> (last visited Nov. 12, 2010) (discussing why Washington D.C. City Council member David Catania thinks the Gardasil vaccine is a particularly important vaccine for young women in Washington D.C. and Virginia) (on file with the Washington and Lee Journal of Civil Rights and Social Justice); *see also* Press Release, Centers for Disease Control, CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination (June 29, 2006), *available at* <http://www.cdc.gov/media/pressrel/r060629.htm> ("This vaccine represents an important medical breakthrough. . . . [T]hese vaccine recommendations address a major health problem for women and represent a significant advance in women's health." (quoting Dr. Anne Schuchat, director of CDC's National Center for Immunization and Respiratory Diseases (internal quotations omitted))) (on file

nationwide.⁶ Among the hotly contested issues are equal protection questions of why vaccination is required only for females, even though the United States Food and Drug Administration (FDA) has also approved Gardasil for men.⁷ Other individuals claim that mandating Gardasil for school attendance violates parental rights and constitutes an improper use of state police power.⁸

Part II of this Note describes HPV's significant impact on the American population and how Gardasil can retard this trend. Part III discusses the extent to which the government can enforce Gardasil vaccination in public schools. This Part includes specific analysis of Virginia's Gardasil vaccination law and concludes that it is a proper use of state police power under the Tenth Amendment and survives constitutional strict scrutiny analysis, but should have narrower exemption provisions.

with the CDC).

6. See Charlotte J. Haug, *Human Papillomavirus Vaccination—Reasons for Caution*, 359 NEW ENG. J. MED. 861, 861 (2008) (noting that "serious questions regarding the overall effectiveness of [Gardasil] in the protection against cervical cancer remain[] to be answered"); see also Elisabeth Rosenthal, *The Evidence Gap: Drug Makers' Push Leads to Cancer Vaccine's Rise*, N.Y. TIMES, Aug. 19, 2008, at A1 (discussing the high cost of Gardasil in comparison to the relatively short amount of studies conducted on the vaccine, as well as noting the connection between Gardasil's manufacturer, Merck, healthcare providers, and politicians).

7. FDA News Release, U.S. Food and Drug Administration, FDA Approves New Indication for Gardasil to Prevent Genital Warts in Men and Boys (Oct. 16, 2009) (on file with the FDA); see also Samuel Broder, *Why Isn't There a Gardasil for Men?*, U.S. NEWS, May 18, 2009, at 1–2 (discussing why Gardasil is not required for men, even though HPV causes penile, anal, and oral cancer in men, as well as anogenital warts); see also Micah Globerson, *Gardasil A Year Later: Cervical Cancer as a Model for Inequality of Access to Health Services*, 15 CARDOZO J.L. & GENDER 247, 251–53 (2009) (stating that new research indicates that HPV causes cancer in men as well as women, and that both genders would benefit from receiving Gardasil). Globerson asserts that Gardasil would be especially beneficial to gay men because they are at high risk for contracting HPV related to anal cancer. *Id.*

8. See Tracy Solomon Dowling, *Mandating a Human Papillomavirus Vaccine: An Investigation into Whether Such Legislation is Constitutional and Prudent*, 34 AM. J.L. & MED. 65, 75–76 (2008) (discussing why parents are opposed to vaccinating their young daughters with Gardasil, specifically for philosophical and moral reasons); see also Julie E. Gendel, *Playing Games with Girls' Health: Why It Is Too Soon to Mandate the HPV Vaccine for Pre-Teen Girls as a Prerequisite to School Entry*, 39 SETON HALL L. REV. 265, 284–88 (finding that there is a parental right to make healthcare decisions for children in most instances, including vaccination decisions); see also *Mandating Gardasil—A Gross Infringement on Parental Rights*, STANDARD NEWSWIRE, Feb. 9, 2010, <http://www.standardnewswire.com/news/57127618.html> (last visited Nov. 12, 2010) (arguing that mandating Gardasil allows government officials to usurp parental rights when making important medical decisions regarding HPV vaccination) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

However, even though mandating Gardasil vaccination is a proper use of state police power and is constitutional under the Due Process Clause, Part IV argues that the Virginia General Assembly should require all boys entering the sixth grade to also be vaccinated with Gardasil to avoid violating the Equal Protection Clause of the United States Constitution.

I. The Impact of Injecting Gardasil into American Society

A. The Human Papillomavirus (HPV)

HPV is a virus that infects the skin by causing normal skin cells to become abnormal.⁹ The Centers for Disease Control and Prevention (CDC) has identified over one hundred different strains of the virus.¹⁰ A majority of these strains are transient, asymptomatic, and do not cause any serious medical conditions.¹¹ In fact, the immune system can naturally clear many strains of the virus from one's body in ninety percent of HPV cases.¹² However, the HPV virus also has other very harmful strains commonly associated with serious medical conditions, particularly cancer.¹³ Approximately twenty million Americans, or fifteen percent of the American population, are currently infected with HPV, and an additional 5.5 million will become infected each year.¹⁴

More than forty strains of the virus are linked to sexually transmitted genital and oral infections.¹⁵ Studies suggest that fifteen percent of the current sexually active adult population in the United States is infected with HPV, and up to eighty percent of the sexually active female population will

9. See Centers for Disease Control and Prevention, *Genital HPV Infection—CDC Fact Sheet*, Nov. 24, 2009, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last visited Feb. 24, 2010) (providing basic factual information about the HPV virus) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. See Centers for Disease Control and Prevention, *A Closer Look at Human Papillomavirus (HPV)*, April 6, 2001, <http://www.cdc.gov/std/Trends2000/HPV-close.htm> (last visited October 30, 2009) (providing statistical information about HPV infection rates in the United States) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

15. See *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9 (providing HPV statistics).

have the virus at some point before age fifty.¹⁶ HPV is extremely contagious because it is spread through skin-to-skin contact and can circumvent the protection of condoms.¹⁷ Other methods of transmission include oral sex, inadequately sanitized sex toys, and newborn delivery cases, where the HPV-infected mother transmits the virus to her baby.¹⁸

The World Health Organization (WHO) classifies two strains of HPV, subtypes 16 and 18, as "high risk" and "carcinogenic."¹⁹ These two strains account for over seventy percent of cervical cancer cases in the United States,²⁰ as well as a significant percentage of vaginal, vulvar, anal, penile, urethral, oral, and neck cancers.²¹ Statistics indicate that 9,700 newly diagnosed cases of invasive cervical cancer and 3,700 deaths from cervical cancer occurred in 2006.²² After breast cancer, cervical cancer is the second deadliest cancer among women worldwide, accounting for twelve percent of all female cancers.²³ CDC statistics also show that over 1,000 men yearly are infected with HPV-related penile cancer, and more than 1,700 men are infected annually with anal cancer caused by the virus.²⁴

HPV strains 6 and 11 account for over ninety percent of anogenital warts cases.²⁵ Research indicates that approximately one percent of the sexually active adult population currently suffers from anogenital warts.²⁶ Warts do not cause cancer,²⁷ but are commonly associated with low-grade cervical disease.²⁸ Less commonly, strains 6 and 11 can cause Recurrent Respiratory Papillomatosis (RRP), a disease in which recurrent warts appear on the larynx and in the respiratory tract, causing airway obstruction

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

17. See Globerson, *supra* note 7, at 249 (describing the sexual transmission of HPV).

18. See *id.* at 250 (describing other modes of HPV transmission besides penetration).

19. Javitt, *supra* note 16, at 385.

20. *Id.*

21. *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9.

22. Javitt, *supra* note 16, at 385.

23. Globerson, *supra* note 7, at 249.

24. *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9.

25. Javitt, *supra* note 16, at 385.

26. *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9.

27. *Id.*

28. Javitt et al., *supra* note 16, at 385.

and possible squamous cell carcinoma.²⁹ A newborn baby can develop RRP through contact with an HPV-infected mother during delivery.³⁰

Because most HPV strains do not cause pain or have easily recognizable symptoms, many people do not know they are infected or that they are transmitting the virus to a partner.³¹ An individual can develop HPV even if years have passed since the last sexual contact with an infected person because certain strains linger in the body.³² It is also possible to be infected with more than one strain of HPV.³³ The lack of recognition or awareness of transmission makes HPV prevention very difficult.³⁴ Furthermore, no general blood test is currently able to check for HPV's overall presence in the body, nor is a specific test available to find HPV on one's skin.³⁵ DNA tests exist that can determine HPV's presence in DNA, but these tests are still widely unavailable, expensive, and often not covered by insurance.³⁶

Women are encouraged to get yearly Papanicolaou (Pap) smears to identify precancerous cervical lesions caused by HPV.³⁷ Pap smears with a follow-up colposcopy have been proven to reduce cervical cancer by nineteen percent.³⁸ Anal Pap smears are also available for detection of the virus in gay and bisexual men.³⁹ Pap smears are relatively costly, and therefore many minority and low-income individuals cannot afford them, thus lowering their chances of detecting HPV before it becomes cancerous.⁴⁰ Some physicians also use a visual inspection with acetic acid (VIA) method.⁴¹ VIA uses common vinegar to blanch white and make visible to the naked eye areas of human sex organs that may be precancerous.⁴² VIA is the most cost-efficient method available, and is

29. *Id.*

30. *Id.*

31. *Genital HPV Infection—CDC Fact Sheet, supra* note 9.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. Globerson, *supra* note 7, at 264.

37. *See id.* at 261 (discussing the value of preventive screenings).

38. *Id.* at 262.

39. *Id.* at 252–53.

40. *See id.* at 262 (stating that poor minorities are least likely to detect HPV before it turns cancerous, largely due to their inadequate access to healthcare).

41. *Id.* at 264.

42. *Id.*

frequently used for poor patients in clinics.⁴³ However, it is also the least effective method, because its reliability is unknown.⁴⁴ Other methods of prevention include condom use to reduce risk of transmission, educating people about safe sex and HPV, abstinence, and, as is discussed in this Note at length, the Gardasil vaccine.⁴⁵

Educated, upper and middle class white women are least likely to develop cervical or vaginal cancer and to die from it, largely due to their ability to receive annual Pap smears and better access to healthcare.⁴⁶ Low-income and minority women are most likely to develop these cancers due to their poor economic status and lack of access to quality healthcare and insurance.⁴⁷ According to the Guttmacher Research Institute, African-American and Latina women are 1.5 times more likely to develop HPV-related cervical, vaginal, and vulvar cancers.⁴⁸ These women are also likely from poor communities that lack funding for sex education in public schools, leaving them uninformed about HPV's prevalence and its devastating effects.⁴⁹ These poor minorities are also the least likely to have access to the Gardasil vaccine.⁵⁰

B. The Gardasil Vaccine

Gardasil is a quadrivalent vaccine protecting against HPV strains 6, 11, 16, and 18.⁵¹ New Jersey-based pharmaceutical corporation Merck &

43. *Id.*

44. *Id.*

45. *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9.

46. *See* Globerson, *supra* note 7, at 261–62 (detailing common medical procedures used to detect HPV, and noting that low-income and minority women are largely unable to benefit from these procedures).

47. *See id.* (stating that poor women have lesser access to quality healthcare and thus are unlikely to detect HPV before it becomes cancerous).

48. *See* Karen Houppert, *Who's Afraid of Gardasil?*, *THE NATION*, Mar. 8, 2007, at 5 (citing a study conducted by the Guttmacher Research Institute that found cervical cancer and HPV disproportionately affect low-income and minority women).

49. *See id.* (describing that poor women are also least likely to learn about the harmful effects of HPV and its high prevalence in American society because schools in these poor communities often lack adequate funding to disseminate this useful preventative information).

50. *See id.* (indicating that low-income and minority women are also the least likely to have access to the relatively expensive Gardasil vaccine).

51. Learn About Gardasil, *supra* note 1.

Co., Inc. (hereafter "Merck") manufactures the vaccine.⁵² In June of 2006, the FDA approved Gardasil for women between the ages of nine and twenty-six.⁵³ In October of 2009, the FDA also approved Gardasil for men.⁵⁴ The CDC and FDA recommend Gardasil for individuals as young as nine because it is most effective when administered before any sexual contact in which HPV may be transmitted.⁵⁵ However, Gardasil is still beneficial to young people who are already sexually active and who even may have possibly been exposed to one of the virus strains, because it is unlikely that the vaccine recipient was already exposed to all four strains that Gardasil protects against.⁵⁶ Clinical studies show Gardasil is one hundred percent effective at preventing infection from strains 6, 11, 16, and 18.⁵⁷

Gardasil is administered in a three-course injection in the arm or thigh over a six-month period.⁵⁸ Side effects are generally mild, and include itching, swelling, and bruising at the injection site, nausea, headache, fever, and fainting.⁵⁹ As of May 31, 2010, the FDA received 16,140 Vaccine Adverse Event Reporting System (VAERS) reports of adverse effects from Gardasil.⁶⁰ Of these, ninety-two percent were non-serious and only eight percent were considered serious.⁶¹ Gardasil has been vaguely linked to fifty-three deaths worldwide.⁶² Twenty-nine of these deaths are confirmed and have been followed up by scientists, and twenty-four remain unconfirmed because no identifiable patient record is available to confirm the report.⁶³ It is important to note that the FDA has not found an unusual

52. FDA News Release, *supra* note 7.

53. *Id.*

54. *See id.* (announcing FDA approval for Gardasil use in boys and men, ages 9 through 26).

55. *See* Learn About Gardasil, *supra* note 1 (describing who should get vaccinated).

56. *See id.* (explaining the preventative value of the vaccine for all sexually active individuals).

57. *See id.* ("GARDASIL is the only human papillomavirus (HPV) vaccine that helps protect against 4 types of HPV.").

58. *Id.*

59. *See id.* (providing side effects of Gardasil).

60. Centers for Disease Control and Prevention, *Reports of Health Concerns Following HPV Vaccination*, June 21, 2010, <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/gardasil.html> (last visited Feb. 29, 2010) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

61. *Id.*

62. *Id.*

63. *Id.*

pattern or clustering effect to the twenty-nine confirmed deaths that would definitively show that they were caused by administration of the vaccine.⁶⁴ Gardasil's link to Guillain-Barre Syndrome (GBS), a rare disease causing muscle deterioration and paralysis affecting one out of every 100,000 people, is also very attenuated.⁶⁵ The CDC reports: "[a] number of infections can cause GBS. There has been no indication that Gardasil increases the rate of GBS in girls and women above the rate expected in the general population, whether or not they were vaccinated [with Gardasil]."⁶⁶ Therefore, the number of reported serious adverse effects and deaths are few when compared to the nearly thirty million Gardasil recipients reporting no complications.⁶⁷

Gardasil is more expensive than most vaccinations, with a retail price of \$120 per shot (or \$360 total).⁶⁸ To date, Merck has garnered between two and four billion dollars in profit from its Gardasil sales.⁶⁹ With Gardasil's recent approval for men, Merck stands to double its profit.⁷⁰

II. Enforcing Gardasil Vaccinations in Public Schools:

To What Extent Can the Government Constitutionally Require Schoolchildren to be Vaccinated with Gardasil?

A. Gardasil Vaccination is a Proper Use of Virginia's Police Power Under the Tenth Amendment

The Tenth Amendment to the United States Constitution states that: "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States."⁷¹ These reserved powers are collectively known as "the state police power."⁷²

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. Wilson, *supra* note 5.

69. *Id.*

70. See Houppert, *supra* note 48 (discussing Merck's possible attempt to corner the vaccine market).

71. U.S. CONST. amend. X.

72. See *Brown v. Md.*, 25 U.S. (12 Wheat.) 419, 443 (1827) (using the phrase "state

*Gibbons v. Ogden*⁷³ held that the state police power extends to inspection, quarantine, and health laws of every description.⁷⁴

The United States Supreme Court first addressed mandatory vaccinations in 1905 in *Jacobson v. Massachusetts*.⁷⁵ The Cambridge Board of Health ordered all city residents to receive the smallpox vaccine due to a smallpox outbreak in the city.⁷⁶ Resident Henning Jacobson challenged the regulation as an unconstitutional exercise of authority over his person.⁷⁷ Justice John Marshall Harlan, writing for the majority, upheld the vaccination regulation as a proper exercise of state police power.⁷⁸ Justice Harlan emphasized that protection of the whole community trumps individual rights in such situations,⁷⁹ noting that "the liberty secured by the Constitution . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. . . . [E]very person is necessarily subject [to] the common good."⁸⁰ At the time,

police power" for the first time); see also *License Cases*, 46 U.S. (5 How.) 504, 583 (1847) (defining the state police power as "nothing more or less than the powers of government inherent in every sovereignty to the extent of its dominions"); see also *Munn v. Ill.*, 94 U.S. 113, 145 (1876) (describing the police power as including "[w]hatever affects the peace, good order, morals and health of the community").

73. See *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (describing the broad extent of a state's police power). In *Gibbons*, the Court held that Congress has plenary power over commerce among the states but also that states have plenary power over matters completely internal within the state. *Id.* at 195–97. The *Gibbons* decision considered a New York statute authorizing a monopoly for a ferry between New York and New Jersey. *Id.* at 234–35. The Court interpreted the Commerce Clause by defining "commerce" as "intercourse between . . . parts of nations." *Id.* at 193. The Court also defined "among the states" as "within the territorial jurisdiction of the several states" and found that commerce having interstate effects fell in that definition. *Id.* at 196.

74. See *id.* at 208 ("The acknowledged power of a State to regulate its police, its domestic trade, and to govern its own citizens, may enable it to legislate . . .").

75. See *Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905) (upholding a Massachusetts statute mandating that an individual be vaccinated against smallpox as appropriate use of police power, despite his objection that the vaccine violated his bodily integrity and right of person). Jacobson objected to the vaccine on the grounds that it violated his liberty to care for his own health. *Id.* at 13. However, the Court reasoned that a state's interest in providing for the common welfare of its citizens outweighed Jacobson's liberty interest. *Id.* at 38.

76. See *id.* at 13 (quoting the Cambridge Board of Health regulation).

77. See *id.* at 13 (arguing that the mandated smallpox vaccination violated the Privileges and Immunities, and Due Process Clauses of the Fourteenth Amendment).

78. See *id.* at 35 (taking judicial notice that the statute reflected the common belief of the people, which provided a proper basis for Massachusetts to exercise its police power).

79. See *id.* at 27 (discussing that the fundamental principles of the Constitution of Massachusetts requires helping the common good over specific individuals).

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

smallpox was rapidly spreading through airborne transmission in Cambridge, and Massachusetts thus had a compelling justification for mandating vaccination.⁸¹ Justice Harlan acknowledged that not all vaccinations can be compelled because a state's police power must be justified by the "necessity of the case" and could not be exercised in an "arbitrary, unreasonable manner" or extend "beyond what was reasonably required for the safety of the public."⁸² Compelling vaccination depends on the degree of danger posed to the community as a whole.⁸³

Jacobson is the leading case in compelled vaccination.⁸⁴ Further Supreme Court cases streamlined, interpreted, and refined it. *Laurel Hill Cemetery v. San Francisco*⁸⁵ held that a state may delegate authority to a municipality to determine under what health conditions certain regulations should become operative.⁸⁶ In *Zucht v. King*,⁸⁷ the Court extended *Jacobson* to permit mandatory smallpox vaccination as a prerequisite to school attendance in Texas.⁸⁸ The Court upheld the vaccination requirement because it was not an "arbitrary power, but only that broad discretion required for the protection of the public health."⁸⁹

Whether government authorities may require child vaccination as a prerequisite to school attendance is an issue much discussed in lower courts

81. *See id.* at 27 ("[A] community has the right to protect itself against an epidemic of disease which threatens the safety of its members.").

82. *Id.* at 28.

83. *See id.* at 28–29 (recognizing that a state's right to pass sanitary and health laws depends on the degree the law would benefit the community as a whole).

84. *See* Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1752–54 (2008) (providing an in-depth analysis of compelled vaccinations in the United States, and stating that *Jacobson* is the seminal case in this legal arena).

85. *See* *Laurel Hill Cemetery v. San Francisco*, 216 U.S. 358, 366 (1910) (holding that San Francisco city officials have the power to enforce an ordinance regulating burial of the dead and cemeteries within city limits). The cemetery asserted that the ordinance was a taking of its property in violation of the Fourteenth Amendment. *Id.* at 363. The Court upheld the ordinance on the grounds that matters of local concern are appropriately decided by local tribunals. *Id.* at 365–66.

86. *See id.* (finding that state and municipal authorities have the authority to regulate health and sanitary laws, specifically regarding burials within San Francisco city limits).

87. *See* *Zucht v. King*, 260 U.S. 174, 176–77 (1922) (requiring smallpox vaccination of schoolchildren in Texas prior to schooling). *Zucht* claimed the San Antonio ordinance requiring vaccination violated her due process rights. *Id.* at 175. The Court dismissed the writ of error because the claim was against a valid exercise of state police power to order compulsory vaccination. *Id.* at 176–77.

88. *Id.*

89. *Id.* at 177.

and state legislatures.⁹⁰ The authority on this subject is not uniform.⁹¹ Some courts hold that a state's power to require vaccination may be exercised without limit because it benefits the community at large.⁹² Other courts and legislatures find that the right to require vaccination should be limited to the presence of an epidemic or emergency in which there is an imminent danger that the disease will infect a significant portion of a given population.⁹³ Still other courts hold that health officials possess the power to require vaccination and may enforce it in cases of necessity, even without legislative authority.⁹⁴ Though approaches to mandatory vaccination vary across state lines, the Supreme Court has held that all vaccination statutes must be reasonable in comparison to the prevalence of the disease in society, and the state must not be motivated by any reason other than protection of the public health.⁹⁵

Almost immediately following FDA approval of Gardasil in June of 2006, twenty-four state legislatures developed laws requiring HPV vaccination of children for school attendance.⁹⁶ In May of 2007, Virginia

90. See generally C.S. Wheatley, Jr., *Power of Municipal or School Authorities to Prescribe Vaccination or Other Health Measures as a Condition of School Attendance*, 93 A.L.R. 1413 (originally published in 1934) (providing a general overview of mandated vaccinations in schools and public municipalities).

91. See *id.* (explaining that some courts require an "emergency" as a prerequisite to requiring vaccination, while other courts hold that the general power exists even in absence of an emergency).

92. See, e.g., *Herbert v. Demopolis Sch. Bd. of Educ.*, 197 Ala. 617, 622–23 (1916) (involving an Alabama ordinance holding that unvaccinated children were not allowed to attend public schools). The court found the statute was an expression of Alabama's police power for the preservation of the public health and was thus valid. *Id.*

93. See, e.g., *Blue v. Beach*, 56 N.E. 89, 91 (Ind. 1900) (interpreting that a statute requiring schoolchildren to be vaccinated as a prerequisite to public school attendance and conferring enforcement of the law upon local health and school boards was not an unconstitutional delegation of legislative power).

94. See, e.g., *Osborn v. Russell*, 68 P. 60, 61 (Kan. 1902) ("[I]t is assumed the legislature has authority to enact such laws as are requisite for the preservation of health, and to prevent infection from contagious diseases, and it may well be that such power can be delegated.").

95. See *Jacobson v. Massachusetts*, 197 U.S. 11, 28–29 (1905) (recognizing that mandating vaccination depends on the benefit the vaccine confers upon the community as a whole).

96. See National Conference of State Legislatures, *HPV Vaccine*, April 2010, <http://www.ncsl.org/IssuesResearch/Health/HPVVaccineStateLegislation/tabid/14381/Default.aspx> (last visited Feb. 28, 2010) (describing various state legislative approaches to mandating Gardasil) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

became the first state to pass such legislation.⁹⁷ The law, codified at VA. CODE ANN. § 32.1-46, currently requires all girls entering the sixth grade to receive the vaccine.⁹⁸ It states, in relevant part:

[T]he parent, guardian or person standing *in loco parentis* of each child within this Commonwealth shall cause such child to be immunized in accordance with the Immunization Schedule . . . for attendance at a public or private elementary, middle or secondary school . . . [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.⁹⁹

The Virginia law as it stands is within the state police power under the Tenth Amendment, as specified in *Jacobson* and subsequent caselaw.¹⁰⁰ The Virginia General Assembly has a clearly compelling health reason—the possibility of an impending health epidemic—to justify its action in promulgating its law. The law is not arbitrary, because it seeks to eradicate a disease affecting the entire Virginia population, and not just specific individuals. Furthermore, Virginia's law does not extend beyond what is reasonably required for the safety of the public because it contains certain vaccination exemptions, discussed further in subpart C below.

B. Gardasil Vaccination Does Not Violate Substantive Due Process Through an Invasion of Bodily Privacy and Unwanted Bodily Intrusion

The constitutionality of mandating vaccination depends upon whether the requirement violates substantive due process concerns of the Fourteenth Amendment, which declares: "No State shall . . . deprive any person of life, liberty, or property, without due process of law . . ." ¹⁰¹ The Supreme Court has held that the liberty interest protected by the Fourteenth Amendment "absorbs and applies to the States . . . express fundamental personal rights," ¹⁰² and that "[l]iberty protects the person from unwarranted government intrusions [And] extends beyond spatial bounds. Liberty

97. *Id.*

98. VA. CODE ANN. § 32.1-46 (2009).

99. *Id.*

100. *See supra* notes 92–95 and accompanying text.

101. U.S. CONST. amend. XIV, § 2.

102. *See Griswold v. Connecticut*, 381 U.S. 479, 488 (1965) (Goldberg, J. concurring) (noting that Justice Goldberg's Concurrence in *Griswold* is most frequently cited for its privacy and substantive due process discussion).

presumes an autonomy of self"¹⁰³ To satisfy substantive due process, laws must be reasonable and not arbitrary.¹⁰⁴ The Supreme Court strictly scrutinizes any law that potentially impairs a fundamental right.¹⁰⁵ In determining whether rights are fundamental, the "inquiry is whether a right involved 'is of such a character that it cannot be denied without violating those fundamental principles of liberty and justice which lie at the base of all our civil and political institutions.'"¹⁰⁶ When strict scrutiny analysis is invoked, the law will be upheld only if it is *necessary* to promote a *compelling* governmental interest.¹⁰⁷

To be held constitutional, Virginia's Gardasil law must pass strict scrutiny analysis because mandatory vaccination implicates the fundamental liberty interests of bodily privacy¹⁰⁸ and protection from unwanted bodily intrusion secured by the Due Process Clause.¹⁰⁹ The Court

103. *Lawrence v. Texas*, 539 U.S. 558, 562 (2003).

104. *See Meyer v. Nebraska*, 262 U.S. 390, 399–400 (1923) ("[T]his liberty may not be interfered with, under the guise of protecting the public interest, by legislative action which is arbitrary or without reasonable relation to some purpose within the competency of the state to effect."); *see also* Kyra R. Wagoner, *Mandating the Gardasil Vaccine: A Constitutional Analysis*, 5 *IND. HEALTH L. REV.* 403, 416 (2008) (stating that in determining the constitutionality of Gardasil vaccination, it is necessary to examine substantive due process concerns under which laws may not be arbitrary and unreasonable).

105. *See Griswold*, 381 U.S. at 503–04 (1965).

106. *See id.* at 493 (quoting *Powell v. Ala.*, 287 U.S. 45, 67 (1932)).

107. *See Regents of Univ. of Cal. v. Bakke*, 438 U.S. 265, 299 (1978) (holding that government-imposed racial classifications in higher education admission schemes must be narrowly tailored to further compelling governmental interests); *see also* *Grutter v. Bollinger*, 539 U.S. 306, 308 (2003) (stating that when race-based action is necessary to further a compelling governmental interest, such action does not violate the constitution so long as the narrow-tailoring requirement is also satisfied); *see also* *Gratz v. Bollinger*, 539 U.S. 244, 270, 280 (holding that an admissions policy at the University of Michigan's undergraduate program was unconstitutional because it was "not narrowly tailored to achieve the interest in educational diversity" and constituted a "nonindividualized, mechanical" decision).

108. *See Griswold v. Connecticut*, 381 U.S. 479, 483 (1965) (majority opinion) (noting that although the Constitution does not expressly recognize a fundamental right to privacy, the Court has recognized "a penumbra where privacy is protected from government intrusion"); *see id.* at 494 (Goldberg, J., concurring) ("[T]he right of privacy is a fundamental personal right, emanating 'from the totality of the constitutional scheme under which we live.'" (quoting *Poe v. Ullman*, 367 U.S. 497, 517 (1961) (Douglas, J., dissenting))).

109. *See* ALAN WESTIN, *PRIVACY AND FREEDOM* 33–38 (Atheneum Publishers, Inc. 1967) (recognizing and discussing privacy interests relating to the "management of bodily and sexual functions"); *see also* *Washington v. Harper* 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty."); *see also* *Palko v. Connecticut*, 302 U.S. 319, 325 (1937) (stating that bodily interests are "implicit in the concept of ordered liberty").

has carved out and analyzed these fundamental liberty interests in a variety of medical and ethical contexts aside from vaccinations,¹¹⁰ including: birth control and contraception,¹¹¹ private sexual conduct,¹¹² continuation of life support,¹¹³ abortion,¹¹⁴ and involuntary sterilization.¹¹⁵ Other issues have risen in similar contexts, such as genetic testing,¹¹⁶ highly-detailed imaging in airport security scanners,¹¹⁷ and forcible administration of drugs.¹¹⁸ In

110. See *Harper*, 494 U.S. at 229 (discussing forcible injection of medication into an individual and finding that this represents a substantial interference with individual liberty).

111. See *Griswold v. Connecticut*, 381 U.S. 479, 499 (1965) (finding that a state law prohibiting the distribution and counseling of contraception for married couples is unconstitutional); see also *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 898 (1992) (affirming constitutional protection of personal decisions relating to procreation and contraception); see also *Eisenstadt v. Baird*, 405 U.S. 438, 443 (1972) (extending *Griswold* to invalidate a state law prohibiting the distribution of contraceptives to unmarried persons).

112. See *Lawrence v. Texas*, 539 U.S. 558, 559 (2003) ("[L]iberty gives substantial protection to adult persons in deciding how to conduct their private lives in matters pertaining to sex.").

113. See *In re Quinlan*, 70 N.J. 10, 24 (1976) ("We think that the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases as the prognosis dims. Ultimately there comes a point at which the individual's rights overcome the State interest."); see also *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 287 (1990) (upholding a state law providing that parents of a woman in a permanent vegetative state could not remove her feeding tube unless they were able to present "clear and convincing evidence" that she would want the tube removed if she were conscious).

114. See *Roe v. Wade*, 410 U.S. 113, 153 (1973) (finding that the due process right to privacy "is broad enough to encompass a woman's decision whether or not to terminate her pregnancy").

115. See *Skinner v. Oklahoma*, 316 U.S. 535, 543 (1942) (invalidating involuntary sterilization of habitual criminals).

116. See, e.g., Complaint, *Beleno v. Tex. Dep't of State Health Servs.*, No. SA09CA0188 (W.D. Tex. Mar. 12, 2009) (dismissed) (discussing the right to bodily integrity in pending litigation regarding involuntary DNA collection and genetic testing from newborn babies in Texas); see also *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269 (9th Cir. 1998) (finding that material facts existed with regards to the constitutionality of subjecting employees to genetic testing without their knowledge or consent).

117. See, e.g., Kate Stanton, *Airport Body Scanners: Security or Invasion of Privacy?*, PUBLIC BROADCASTING SERVICE, Jan. 12, 2010, available at http://www.pbs.org/newshour/extra/features/us/jan-june10/security_01-12.html (discussing the right to bodily privacy regarding new airport security scanners that reveal highly-detailed images of the human body) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

118. See *Mills v. Rogers*, 457 U.S. 291, 293 (1982) (discussing whether involuntarily committed mental patients have a constitutional right to refuse treatment with antipsychotic drugs); see also *Sell v. United States*, 539 U.S. 166, 186 (2003) (finding that forcible administration of anti-psychotic drugs is acceptable under certain limited circumstances). The Court found that forcible drugging can significantly further important governmental interests in achieving a fair and speedy trial, but limits must exist on the circumstances in

general, a state's interest in a medical or ethical issue will be upheld if it is compelling and necessary to protect the public at large.¹¹⁹ For example, in *Schmerber v. California*,¹²⁰ law enforcement officials obtained a blood sample from an unconscious defendant to determine his blood alcohol level and prove that he was driving under the influence of alcohol.¹²¹ The Court recognized that "to invade another's body in search of evidence of guilt is indisputable and great."¹²² Nonetheless, the Court allowed the extraction because a blood sample constitutes only a "minor intrusion[]"¹²³ on the defendant's body that was outweighed by California's interest in prosecuting drunk drivers and securing evidence of blood-alcohol content incident to the defendant's arrest.¹²⁴ In doing so, the Court noted that blood

which a court can permit the State to forcibly drug someone. *Id.* at 179. There must be no alternative, less intrusive means to achieve the same results that forcible drugging might bring, and the administration of drugs must be medically appropriate. *Id.* See also *Palko v. Connecticut*, 302 U.S. 319, 327 (1937) (recognizing that bodily intrusion and physical security interests are "implicit in the concept of ordered liberty"); see also *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 287 (O'Connor, J., concurring) ("[T]he Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause."); see also *United States v. Stanley*, 483 U.S. 669, 710 (1985) (O'Connor, J., concurring in part and dissenting in part) (quoting the Nuremberg Tribunal's finding that "voluntary consent of the human subject [to medical experimentation] is absolutely essential . . . to satisfy moral, ethical, and legal concepts" (internal quotations and citations omitted)).

119. See *Cruzan*, 497 U.S. at 262 (1990) ("The State may also properly decline to make judgments about the 'quality' of a particular individual's life and simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual.")

120. See *Schmerber v. California*, 384 U.S. 757, 772 (1966) (finding that a blood sample taken from an unconscious defendant did not violate the defendant's Fourth Amendment rights against unconstitutional search and seizure). The defendant in question was hospitalized following a car accident. An officer smelt liquor on him and the defendant showed other signs of intoxication. The forced blood sample taken at the hospital was subsequently used to convict him at trial. *Id.* at 769. The Court justified its decision based on the particular circumstances of the case at hand: "Particularly in a case such as this, where time had to be taken to bring the accused to a hospital and to investigate the scene of the accident, there was no time to seek out a magistrate and secure a warrant. Given these special facts, we conclude that the attempt to secure evidence of blood-alcohol content in this case was an appropriate incident to petitioner's arrest." *Id.* at 770–71.

121. *Id.* at 758–59.

122. *Id.* at 770.

123. *Id.* at 772.

124. See *id.* at 770–71 ("The officer . . . might reasonably have believed that he was confronted with an emergency [that] . . . threatened 'the destruction of evidence' . . . [T]he percentage of alcohol in the blood . . . diminish[es] shortly after drinking stops, . . . Given these special facts . . . the attempt to secure evidence of blood-alcohol content . . . was an appropriate incident to petitioner's arrest." (internal quotations and citations omitted)).

samples are reasonable and commonplace procedures in today's society that involve minimal pain, risk, and trauma.¹²⁵ More recently in 2003, the Court addressed the forcible administration of anti-psychotic drugs to a mentally ill defendant facing serious criminal charges in order to render him competent to stand trial in *Sell v. United States*.¹²⁶ The Court upheld the forcible drug administration because it significantly benefitted the government's interest in achieving a fair and speedy trial.¹²⁷ However, this ruling was not without limitation. Specifically, the Court stated that no alternative and less intrusive means of achieving the same result were available and that the drug administration was medically appropriate given the circumstances.¹²⁸ Therefore, in both *Schmerber* and *Sell*, the Court indicates that rights to bodily privacy and protection from unwanted bodily intrusion may be superseded if the State offers compelling and necessary reasons to do so.

Similar to the Court's approach in *Schmerber* and *Sell*, Virginia may supersede rights to bodily privacy and protection from unwanted bodily intrusion with its Gardasil mandate because it has a compelling and necessary governmental interest in protecting the public health from HPV's harmful and widespread effects.¹²⁹ *Jacobson* ruled that vaccination may be

125. See *Schmerber*, 384 U.S. at 771 ("[W]e are satisfied that the test chosen to measure petitioner's blood-alcohol level was a reasonable one. Extraction of blood samples [] is a highly effective means of determining the degree to which a person is under the influence of alcohol. Such tests are [] commonplace . . . and . . . involve[s] virtually no risk, trauma, or pain." (internal citations omitted)).

126. See *Sell v. United States*, 539 U.S. 166, 186 (2003) (allowing forcible administration of anti-psychotic drugs to a defendant to determine if he was competent to stand trial). Charles Sell had a long history of mental illness. *Id.* at 169. In the courtroom, he was "out of control" and ruled mentally incompetent to stand trial. *Id.* at 170. The government showed that anti-psychotic medication was the only way to render him less dangerous. *Id.* at 185. The Court set out four factors that should be examined before forcible administrations of this kind:

First, a court must find that *important* governmental interests are at stake . . . Second, the court must conclude that involuntary medication will *significantly further* those concomitant state interests . . . Third, the court must conclude that involuntary medication is *necessary* to further those interests . . . Fourth, as we have said, the court must conclude that administration of the drugs is *medically appropriate* . . .

Id. at 180–81.

127. See *id.* at 167 (noting the importance of a fair and speedy trial).

128. See *id.* ("[T]he court must conclude that involuntary medication is *necessary* to further those interests and find that alternative, less intrusive treatments are unlikely to achieve substantially the same results [T]he court must [also] conclude that administering the drugs is *medically appropriate*.").

129. See *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9 (explaining that some

mandated under appropriate circumstances and when considering factors such as the risk to the public of contracting the disease, reasonableness of a risk-benefit analysis, and the extent of intrusion on personal autonomy.¹³⁰ In *Zucht*, the Court clarified that an emergency does not need to exist in order for the state to require vaccination, as long as existing conditions constitute a "menace to public health."¹³¹ Subsequent lower courts interpreting this Supreme Court precedent have found that states can require immunization for school attendance whenever "reasonably necessary or proper,"¹³² and that "any regulation intended and reasonably calculated to prevent the introduction or spread of [any] contagion among schoolchildren bears a direct and very intimate relation to the maintenance of efficient schools."¹³³

HPV certainly constitutes a "menace to [the] public health"¹³⁴ because of its widespread effects and easily transmitted mode of infection.¹³⁵ Gardasil can reduce this menace by potentially saving thousands of lives because it is proven to be one hundred percent effective in eliminating two high-risk HPV strains associated with numerous cancers.¹³⁶ Gardasil can also save future generations of innocent children the pain and suffering of maternally transmitted RRP.¹³⁷ HPV is rampant in American society because its skin-to-skin mode of transmission often circumvents condoms, and because actual penetration is not necessary to transmit the virus.¹³⁸

HPV types can cause cervical cancer and that at least fifty percent of sexually active men and women get it at some point in their lives).

130. See Rebecca E. Skov, *Examining Mandatory HPV Vaccination for All School-Aged Children*, 62 FOOD & DRUG L.J. 805, 815 (2007) (discussing subsequent interpretations of *Jacobson*).

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

132. See *Booth v. Bd. of Educ.*, 70 S.W.2d 350, 352 (Tex. Civ. App. 1914) (holding that the Board of Education can require immunization of children to start public schooling, so long as the action is not "arbitrary").

133. See *Johnson v. Dallas*, 291 S.W. 972, 973 (Tex. Civ. App. 1927) (holding that when mandating compulsory vaccination, the Board of Education acted within its authority).

134. *Zucht*, 260 U.S. at 177.

135. See *infra* notes 138–40 and accompanying text (noting the devastation that results from HPV).

136. See Javitt et al., *supra* note 16, at 385 ("Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by vaccine-type HPV").

137. See *id.* (describing harmful and painful effects of RRP in children).

138. See Globerson, *supra* note 7, at 250 (detailing how HPV is more easily transmitted than other STDs because of its transmission through skin-to-skin contact, oral sex, and inadequately sanitized sex toys).

Even though over twenty million Americans are HPV carriers, most have no noticeable signs and symptoms.¹³⁹ Moreover, up to eighty percent of the sexually active female population will likely be infected with the virus before age fifty.¹⁴⁰ These reasons and statistics offered in support of Virginia's Gardasil mandate are certainly compelling in light of HPV's widespread and devastating effects across the state and nationwide.

Opponents of the Virginia law assert that Gardasil should not be mandatory for a disease that can be prevented by behavioral modification.¹⁴¹ Because HPV is primarily contracted sexually, and not by activities in which students are engaged in at school, the disease is not directly communicable in a school setting in the same manner as chicken pox, mumps, measles, and smallpox.¹⁴² According to this argument, because young students are not—or at least should not be—having sexual contact in the school environment, Gardasil vaccination is not necessary and constitutes an invasion of bodily privacy through forced injection of an unwanted agent.¹⁴³ These individuals further claim that Gardasil encourages early sexual activity and grants young girls a license to freely engage in premarital sex.¹⁴⁴ As Nancy Gibbs explains in *Defusing the War Over the "Promiscuity" Vaccine*, "[t]here may well be parents who are reluctant to give their nine-year-old in pigtails a vaccine against a sexually transmitted disease"¹⁴⁵ These parents are not only concerned that their young daughters will start having sex at an early age, but also worry that

139. *Genital HPV Infection—CDC Fact Sheet*, *supra* note 9.

140. Javitt et al., *supra* note 16, at 385.

141. *See* Law, *supra* note 84, at 1756 ("One argument against the HPV vaccine mandate is that, unlike infectious diseases transmitted through the air or through casual contact, HPV is transmitted through sexual contact that can be avoided.").

142. *See* Dowling, *supra* note 8, at 75 ("The HPV vaccine is different from other childhood vaccines because it prevents a disease that is almost never spread without sexual contact.").

143. *See id.* at 76 (discussing parental concerns with vaccinating young girls).

144. *See* Nancy Gibbs, *Defusing the War Over the "Promiscuity" Vaccine*, TIME MAGAZINE, Jun. 21, 2006, available at <http://www.time.com/time/printout/0,8816,1206813,00.html> (discussing the effects of Gardasil on potential early sexual promiscuity, and parental fears that Gardasil could actually encourage unprotected sexual activity) (on file with the Washington and Lee Journal of Civil Rights and Social Justice); *see also* Kyra R. Wagoner, *Mandating the Gardasil Vaccine: A Constitutional Analysis*, 5 IND. HEALTH L. REV. 403, 417 (2008) (describing parental fears that Gardasil will promote early sexual activity because it gives teens a false sense of confidence); *see also* Wilson, *supra* note 5, at 2 ("Some conservatives object to the vaccine because they fear it will encourage early sexuality."); *see also* Houppert, *supra* note 48, at 2 ("Cultural conservatives and abstinence-only hardliners have been trotting out familiar arguments: safe sex leads to more sex.").

145. Gibbs, *supra* note 144, at 5.

Gardasil will give their daughters a false sense of confidence from a failure to realize that it does not protect against all HPV strains and other sexually transmitted diseases.¹⁴⁶

However, this argument seriously underestimates the high prevalence of sexual conduct occurring among teens today, regardless of whether or not they have been vaccinated with Gardasil.¹⁴⁷ Government studies show that six percent of girls in the United States have had sex by age thirteen.¹⁴⁸ This number increases to over seventy percent by age eighteen.¹⁴⁹ However, no studies to date prove that inoculation with a vaccine against a sexually transmitted virus leads girls to experiment sexually at a younger age.¹⁵⁰ Furthermore, not all sex is consensual, and HPV can certainly be transmitted through rape and child molestation.¹⁵¹ One in six American women is a victim of sexual assault, and forty-four percent of rape victims are under age eighteen.¹⁵² Because Gardasil is most effective before an individual has had sexual contact, immunizing young girls before they have sex makes sense for all the above reasons.¹⁵³ As Kim Gandy, President of The National Organization for Women, states: "[o]pposing an effective vaccine that would save hundreds of thousands of women's lives with the vacuous assertion that it would lead to promiscuity is inexcusable."¹⁵⁴

146. *See id.* at 3–5 (describing parental arguments that Gardasil can lead to an increase in unsafe sexual behavior due to mistaken perceptions of safety and that Gardasil will give their young daughters a false sense of confidence because the vaccine only protects against four strains of HPV).

147. *See Skov, supra* note 130, at 828 (discussing the high prevalence of sexual conduct among teens today, often without the protection of Gardasil or condoms).

148. *Id.*

149. Gibbs, *supra* note 144, at 2.

150. *See Skov, supra* note 130, at 828 (stating that there are currently no studies available that indicate that inoculation against HPV leads to greater sexual promiscuity); *see also* Gibbs, *supra* note 144, at 2 ("In contrast to the strong scientific evidence supporting the effectiveness of the cervical cancer vaccine, there is no scientific evidence to support the fear that its use will promote sexual activity.").

151. *See Skov, supra* note 130, at 822 ("[O]ppo[nents of] mandatory vaccination with the vaccine seem to ignore that many young women, especially those in college, are subjected to date rape and other types of sexual assault.").

152. *See id.* (stating that rape is a common, but unfortunately underreported, occurrence among young women). According to the Rape Abuse and Incest National Network (RAINN), young women are four times more likely than any other identifiable group to be victims of sexual assault and sadly, only twenty-six percent of these rapes are reported. *Id.*

153. *See Learn About Gardasil, supra* note 1 (indicating that Gardasil is most effective at fully preventing HPV subtypes 6, 11, 16, and 18 when administered before any sexual contact occurs in which the virus may have been transmitted).

154. Gibbs, *supra* note 144, at 2.

Opponents of the Virginia law also argue that Gardasil is relatively new and its long-term effectiveness is unknown, thereby making the law arbitrary.¹⁵⁵ These individuals assert that they are unwilling to subject children to potentially harmful side effects of the vaccine, such as fainting, nausea, rash, headaches, and possibly Guillain-Barre Syndrome (GBS).¹⁵⁶ However, this argument cannot stand in light of the fact that Gardasil is shown to be safe and one hundred percent effective in reducing anogenital warts and life-threatening cancers.¹⁵⁷ This benefit overwhelmingly outweighs the cost of mild side effects that almost all vaccines administered today have as well.¹⁵⁸ Only fifty-three deaths worldwide are vaguely linked to Gardasil, and it is unknown whether they were attributable to pre-existing medical conditions or interactions with other vaccinations received simultaneously.¹⁵⁹ Moreover, GBS is a very rare disease and its link to Gardasil is extremely attenuated.¹⁶⁰ Thus, the incidence of serious adverse events from Gardasil is very low.¹⁶¹ In fact, in June of 2007, Dr. John Iskander of the CDC's Advisory Committee on Immunization Practices presented data at a CDC Advisory Committee Panel showing that serious adverse effects associated with Gardasil are rare: "[T]he serious adverse event reporting rate is [only] 1.8 per 100,000 doses [of Gardasil]."¹⁶² If

155. See Houppert, *supra* note 48, at 3 (quoting Barbara Loe Fisher, Head of The National Vaccine Information Center, as saying: "[o]ur concern is that this vaccine has not been studied long enough, or in enough children, to start mandating its use"); see also Skov, *supra* note 130, at 822 (detailing The Vaccination Liberation Organization's opposition to Gardasil which questions its effectiveness and duration of immunity).

156. Learn About Gardasil, *supra* note 1.

157. See Wagoner, *supra* note 144, at 418 (articulating the significant effectiveness of Gardasil).

158. See *id.* at 418–19 (describing that most vaccines and medications have similar side effects).

159. See *Reports of Health Concerns Following HPV Vaccination*, *supra* note 60 (noting that as of May 31, 2010, the FDA has received 16,140 VAERS reports of adverse effects from Gardasil and of these, ninety-two percent were non-serious and only eight percent were considered serious). Gardasil has been vaguely linked to fifty-three deaths worldwide. *Id.* Twenty-nine of these deaths have been confirmed, and twenty-four remain unconfirmed because no identifiable patient records are available to confirm the report. *Id.* The FDA has found no unusual pattern or clustering to the twenty-nine confirmed deaths that would solidify that they were caused by administration of the vaccine. *Id.*

160. See *id.* (describing a CDC statement to the press stating that the number of GBS infections related to Gardasil are extremely low).

161. See *id.* (noting that after administering approximately 29.5 million doses of Gardasil, VAERS reports 16,140 adverse events, considering only eight percent "serious").

162. See Wagoner, *supra* note 144, at 419 (quoting Dr. John Iskander of The CDC Advisory Committee on Immunization Practices).

Gardasil has actually injured any individuals, they can recover under the 1986 National Vaccine Injury Compensation Program Act.¹⁶³ The Program has covered Gardasil since February of 2007, and no claims involving the vaccine have been filed to date.¹⁶⁴ Furthermore, almost all major health organizations, including The American Academy of Pediatrics, The Society for Adolescent Medicine, and The American College of Obstetricians and Gynecologists, strongly recommend Gardasil and are confident that its benefits outweigh the minimal costs.¹⁶⁵

Other parents and conservatives oppose the large number of vaccines students are already required to receive prior to school attendance.¹⁶⁶ In the 1980s, children in most states were required to receive twenty-three doses of seven different vaccines by age six.¹⁶⁷ Today, the number of required vaccinations in most states has doubled, with children required to receive forty-eight doses for fourteen different vaccines by age six.¹⁶⁸ However, these individuals opposing Gardasil vaccination fail to notice that vaccination requirements "do not exist solely to prevent the transmission of disease in school or during childhood. Instead, they further society's strong interest in ensuring people are protected from disease throughout their lives and are a highly efficient means of eradicating disease in the larger

163. *See id.* (stating that The National Vaccine Injury Compensation Program provides a no-fault compensation plan with damages for pain and suffering capped at \$250,000 for individuals injured by federally-regulated vaccines).

164. *Id.*

165. *See* Houppert, *supra* note 48, at 3 (stating that several major health organizations support the administration of Gardasil). Houppert quotes Dr. Neal Halsey of The Department of International Health and Pediatrics at Johns Hopkins Bloomberg School of Health as saying: "This is a remarkably safe vaccine. There is no evidence of an increased risk of serious adverse effects." *Id.*

166. *See* Wagoner, *supra* note 144, at 418–19 (citing reasons why individuals are opposed to mandatory Gardasil vaccination); *see also* Wilson, *supra* note 5, at 2 ("[S]ome parents object to vaccines because they think their kids are already subjected to too many as it is."); *see also* Dowling, *supra* note 8, at 76 (stating that many parents are concerned about the large amounts of vaccinations children receive today prior to schooling and noting that they would prefer to limit the number of vaccinations to those that are strictly necessary); *see also* Jeffrey Dach, *Guard Your Daughter from Gardasil*, May 6, 2007, <http://jeffreydach.com/2007/05/06/jeffreydachdrdachvaccinehpv.aspx> (last visited Nov. 12, 2010) (listing thirteen reasons against Gardasil administration to young girls, including unknown vaccine efficacy and lack of testing in the preteen age group) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

167. *See* Wagoner, *supra* note 144, at 418 (indicating the high volume of vaccines children must receive today in order to be eligible to attend public schools).

168. *Id.*

community."¹⁶⁹ The United States currently has the lowest rates of vaccine-preventable diseases.¹⁷⁰ This success has drastically decreased once common childhood diseases and has significantly improved morbidity and mortality rates in the general population.¹⁷¹ For example, all states currently require students to be immunized against rubella, even though the disease is usually mild in children and is administered primarily to protect pregnant women from the devastating effects rubella can have on a developing fetus.¹⁷² Likewise, every state requires immunization against tetanus, even though the disease is not spread through human contact.¹⁷³ Most states also require vaccination against the chicken pox before children begin schooling, even though morbidity rates from the infection are only between 100 to 150 deaths annually.¹⁷⁴ Most notably, a majority of states also require Hepatitis B inoculation.¹⁷⁵ Hepatitis B is a virus spread primarily through sexual contact or intravenous drug use that causes liver malfunction leading to chronic liver failure and cirrhosis.¹⁷⁶ As with HPV, people can reduce the risk of contracting Hepatitis B by refraining from engaging in sexual activity and recreational drug use.¹⁷⁷ But unlike HPV, Hepatitis B has a very low mortality rate of only 0.1%, compared to the 35.4% mortality rate of cervical cancer caused by HPV.¹⁷⁸ Despite the low mortality rate, since 1991 the CDC has recommended the Hepatitis B

169. Cynthia Dailard, *Achieving Universal Vaccination Against Cervical Cancer in the United States: The Need and the Means*, 9 GUTTMACHER POL'Y REV. 12, 14 (2006).

170. See Law, *supra* note 84, at 1733 n.1 (stating that mandating vaccination as a prerequisite to schooling in the United States has drastically lowered rates of several harmful and possibly deadly diseases, including mumps, measles, polio, and Hepatitis B).

171. See James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 878 (2001) (citing numerous public health studies which conclude that school vaccination requirements have significantly benefitted the public health over time through eradication of once harmful and deadly diseases).

172. See Law, *supra* note 84, at 1757 (discussing rubella vaccination requirements for schoolchildren).

173. See *id.* (discussing required tetanus inoculations for schoolchildren).

174. See Dowling, *supra* note 8, at 824 (noting that these morbidity rates are relatively low).

175. See Skov, *supra* note 130, at 824 (noting that it is now standard practice for newborns to receive the Hepatitis B vaccine before departure from the maternity wing of the hospital).

176. See *id.* at 824 (describing how Hepatitis B is spread among people).

177. See *id.* (noting that both HPV and Hepatitis B are spread through sexual contact, and that the risk of transmission of either disease can be significantly reduced by refraining from engaging in sexual activity).

178. *Id.*

vaccine for all newborns before release from the hospital.¹⁷⁹ These statistics and the policies recognizing them strengthen the argument for mandating HPV vaccination for schoolchildren and demonstrate that the Virginia law is not arbitrary.

Another argument against mandating HPV vaccination in Virginia is that Gardasil's high price tag of \$360 and frequent lack of insurance coverage for it can create a significant financial hardship, especially for low-income and minority families.¹⁸⁰ However, although Gardasil is a relatively expensive vaccine, the Virginia law can actually help to narrow the gap between poor minorities with inadequate healthcare and affluent individuals with access to better quality care.¹⁸¹ A disproportionate number of poor and minority females suffer from cervical cancer and die unnecessarily from it because they are uninsured and unable to pay for annual Pap smears and regular STD testing.¹⁸² Moreover, studies show that girls between the ages of eleven and fourteen have the least regular source of medical care in the United States among women.¹⁸³ The Virginia General Assembly is targeting this precise age group with its Gardasil law. By requiring Gardasil, these under-served populations that would not otherwise be reached can be immunized against HPV.¹⁸⁴ Dr. Deborah Arrindell, Vice-President of Health Policy at The American Social Health Organization, believes that "[m]iddle school may be the last public health gate we all walk through together, before kids begin dropping out of

179. *Id.*

180. *See* Wilson, *supra* note 5, at 2 (discussing Gardasil's high price and how this impacts low-income and minority families); *see also* Gibbs, *supra* note 144, at 4 ("If it's available in theory but it costs \$375, it's not available to everybody." (quoting Dr. Karen Loeb Lifford, a Boston OBGYN who serves as the medical director for Planned Parenthood of Massachusetts)).

181. *See* Law, *supra* note 84, at 1764 ("The positive impact of making a vaccine mandatory is greatest for low-income people and racial minorities.").

182. *See id.* at 1764–65 (stating that women of color are more likely to be poor and uninsured and that even when researchers account for wealth, insurance, education, medical conditions, test results and other influential factors, women of color still receive inferior medical care in comparison to white women). As a result, Law notes that it is not surprising that there are marked racial and ethnic disparities in immunization levels among adults. *Id.*

183. *See id.* at 1747–48 (noting that this statistic is due to an existing binary in healthcare today, where almost all infants receive adequate care when they are born in hospitals and older women have an incentive to seek medical treatment for more readily apparent health problems, leaving young female adolescents lost in the middle with irregular and inadequate care).

184. *See* Houppert, *supra* note 48, at 3 (describing how low-income and minority women are the least likely to receive quality healthcare and access to the Gardasil vaccine, and finding that mandatory vaccination may help overcome this problem).

schools or get a crummy job without health insurance, or enter the workforce in general with its fragmented healthcare system."¹⁸⁵ Therefore, the benefit of preventing a potentially deadly disease in low-income and minority girls offsets the burden felt by Gardasil's high price tag.¹⁸⁶

Moreover, the Federal Government recognizes that Gardasil is a necessary but relatively expensive vaccine. To ease the financial burden felt by certain families, the Federal Government provides free vaccination for children up to age eighteen who are Medicaid eligible and uninsured in its Vaccine for Children Program.¹⁸⁷ The Federal Government also provides support to low-income individuals through the Section 317 Immunization Grant Program, which gives state governments money to help vaccinate particularly vulnerable groups.¹⁸⁸ Merck also created its own program designed to provide Gardasil to individuals falling below two hundred percent of the national poverty line.¹⁸⁹ By making Gardasil vaccination mandatory for school admission in Virginia, the Virginia General Assembly actually promotes the compelling interest of improving the State's public health overall.

Lastly, it is argued by some individuals that the Gardasil mandate is so vigorously advocated because Merck is a high-powered lobbyist of the U.S. Senate and House of Representatives and many state legislatures, including Virginia.¹⁹⁰ These individuals believe that Merck desperately needed to recover its image in the pharmaceutical industry after the FDA withdrew its

185. *See id.* at 3 (quoting Dr. Deborah Arrindell, Vice-President of Health Policy at The American Social Health Organization).

186. *See* Globerson, *supra* note 7, at 262 (discussing the high level of HPV prevalence in poor and minority communities).

187. *See* Centers for Disease Control and Prevention, *Programs & Tools: VFC: For Parents*, July 2, 2010, available at <http://www.cdc.gov/vaccines/programs/vfc/parents/default.htm> (explaining the parameters of eligibility) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

188. *See* Department of Health and Human Services, Centers for Disease Control and Prevention: Section 317 Immunization Program, <http://www.hhs.gov/recovery/programs/cdc/immunizationgrant.html> (last visited Nov. 12, 2010) (providing funding for "immunization operations and infrastructure") (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

189. *See* Dailard, *supra* note 169, at 15–16 ("In response to all this, Merck in May announced it would create a new 'patient assistance program,' designed to provide all its vaccines free to adults who are uninsured, unable to afford the vaccines and have an annual household income below 200% of the federal poverty level (\$19,600 for individuals and \$26,400 for couples).").

190. *See* Law, *supra* note 84, at 1757 ("Merck is one of the seven largest pharmaceutical companies in the world and holds the exclusive right to market the HPV vaccine in the United States. Merck has a history of aggressive marketing.").

widely distributed arthritis medication, Vioxx, from the market in 2004.¹⁹¹ Furthermore, Merck competitor GlaxoSmithKline, Inc. recently received FDA approval for its own HPV vaccine.¹⁹² Therefore, Gardasil opponents assert Merck has a significant financial stake in school vaccination laws, and that the laws are a conspiracy between Merck and the government to collect a significant profit for Merck.¹⁹³ However, this argument cannot stand because no significant evidence exists linking Merck to such a conspiracy.¹⁹⁴ In fact, many medical professionals view Merck's aggressive Gardasil campaign as a form of public education to inform people about HPV and cervical cancer.¹⁹⁵ Even accounting for the large financial stake Merck has in school vaccination laws, Dr. Sydney Wolff, Head of The Public Citizen Health Research Group, concludes that "just because self-interested corporate behavior is at the root of an initiative does not prove that the initiative is not worthwhile. Cervical cancer takes the lives of some 3,700 American women each year. Preventing these deaths . . . is obviously an end worth pursuing."¹⁹⁶ In fact, as of February 2007, Merck suspended its lobbying campaign to persuade state governments to make Gardasil vaccination mandatory.¹⁹⁷

191. See Houppert, *supra* note 48, at 2–3 (describing why individuals are suspicious of Merck's motives in advocating Gardasil); see also Law, *supra* note 84, at 1756 (noting that Merck holds the exclusive right to market Gardasil in the United States, leading many individuals to believe Merck has solely self-interested financial motives for promoting the vaccine).

192. See *FDA Approves Cervarix, GlaxoSmithKline's Cervical Cancer Vaccine*, Oct. 16, 2009, available at http://www.gsk.com/media/pressreleases/2009/2009_pressrelease_10112.htm (stating that on October 16, 2009, GlaxoSmithKline received FDA approval for its own HPV vaccine, Cervarix, to market and sell in the United States, which is approved to protect individuals against HPV subtypes 16 and 18) (on file with the Washington and Lee Journal of Civil Rights and Social Justice). Clinical studies of the drug show some degree of cross-protection from HPV subtypes 31 and 45 as well, which Gardasil does not protect against. *Id.* Cervarix is currently approved and offered in twenty-seven European Union members states, Australia, Brazil, South Korea, Taiwan, Mexico, and the Philippines. *Id.*

193. See Houppert, *supra* note 48, at 2 (discussing opposition to the vaccine and Merck's possibly wrongful motivation in its aggressive campaigning for Gardasil).

194. See Law, *supra* note 84, at 1758–60 (discussing Merck's role in mandating Gardasil for schoolchildren and stating that there is no evidence indicating Merck has participated in a conspiracy to garner a significant profit as a high-profile lobbyist).

195. See *id.* at 1758 (responding to critics who believe the Merck campaign is exaggerating problems associated with HPV in order to create a larger market). The vaccine proponents argue that Merck's campaign should be viewed as a public education program to inform people of a problem of which they are not aware. *Id.*

196. *Id.* at 1759–60.

197. See *id.* at 1760 (stating that Merck has suspended its aggressive Gardasil lobbying campaign in response to harsh criticism from the media and concerned parents).

In sum, the Virginia Gardasil mandate should be upheld for children entering the sixth grade—subject to certain exemptions discussed in subpart C—in order to promote Virginia’s necessary and compelling interest of protecting the public health from the harmful and widespread effects of HPV. The Virginia General Assembly acted reasonably in promulgating this necessary law because it responded to a compelling health risk causing thousands of deaths annually.¹⁹⁸ Gardasil does not pose a significant health risk to its recipients and is proven to be safe and one hundred percent effective.¹⁹⁹ Because the requirement can be waived for certain reasons detailed below in subpart C, it is also not an unfair or unreasonable law. Therefore, the Virginia mandate passes strict scrutiny analysis and is constitutional under the Due Process Clause of the U.S. Constitution.

C. Exemptions from Mandated Vaccination and Parental Rights

Mandating HPV vaccination is necessary and the government has compelling reasons to do so. However, compelled vaccination of schoolchildren raises an apparent conflict between regulating public health and parental rights.²⁰⁰ One way in which states seek to mitigate this conflict is through vaccination exemptions for certain individuals or for specific reasons.²⁰¹

The Supreme Court has recognized parental rights as fundamental for purposes of the Due Process Clause of the Fourteenth Amendment.²⁰²

198. See Dowling, *supra* note 8, at 79 (discussing the Virginia General Assembly’s motivation in drafting and promulgating its Gardasil law).

199. See *Reports of Health Concerns Following HPV Vaccination*, *supra* note 60 (noting that Gardasil is safe and one hundred percent effective in preventing transmission of four harmful HPV subtypes).

200. See Law, *supra* note 84, at 1765–66 (discussing how mandating vaccinations can cause conflicts between the public interest and individual rights); see also Gendel, *supra* note 9, at 284–88 (2009) (arguing that parental rights are infringed upon by mandating HPV vaccination in public schools); see also Skov, *supra* note 130, at 822–23 (discussing general parental acceptance and rejection attitudes toward Gardasil); see also Dowling, *supra* note 8, at 75 (“Parents rely on their own attitudes, values, and life experiences to decide whether or not they approve administering the HPV vaccine to their daughters.”).

201. See Law, *supra* note 84, at 1765–66 (stating that many state governments provide exemptions from vaccines to certain individuals and for varying reasons in an attempt to alleviate the conflict between individual rights and the public interest in preventing spread of communicable diseases).

202. See *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 534–35 (1925) (finding that the right to educate one’s children as one chooses is made applicable to the States by the force of the

*Meyer v. Nebraska*²⁰³ recognized the right to "establish a home and bring up children" as a fundamental right subject to strict scrutiny analysis.²⁰⁴ Parents traditionally make medical decisions for their minor children.²⁰⁵ When the government intrudes on choices concerning the family, such as medical care for children, courts "must examine carefully the importance of the governmental interests advanced and the extent to which they are served by the challenged regulation."²⁰⁶ The government "is not without constitutional control over parental discretion in dealing with children when their physical or mental health is jeopardized,"²⁰⁷ and the State may override parental objections if they could result in harm to children or the community at large.²⁰⁸ Therefore, courts must strictly scrutinize the Virginia Gardasil law to determine if it encroaches upon the fundamental right to parenting. If the Virginia General Assembly can offer compelling

First and Fourteenth Amendments); *see also* *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977) (establishing that "the Constitution protects the sanctity of the family precisely because the institution of the family is deeply rooted in this nation's history and tradition"); *see also* *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965) (recognizing a familial and marital right under the Constitution). "[Marriage] is an association that promotes a way of life, not causes; a harmony in living, not political faiths; a bilateral loyalty, not commercial or social projects." *Id.* *See also* *Roe v. Wade*, 410 U.S. 113, 152 (1973) ("[T]he right [of privacy] has some extension to activities relating to marriage, procreation, contraception, family relationships, and child rearing and education."); *see also* *Poe v. Ullman*, 367 U.S. 497, 517 (1961) (Holmes, J., dissenting) ("The home derives its pre-eminence as the seat of family life. And the integrity of that life is something so fundamental that it has been found to draw to its protection the principles of . . . Constitutional right[s]."); *see also* *Troxel v. Granville*, 530 U.S. 57, 87 (2000) (holding that a state government needs a more compelling reason to interfere with parental rights than the fact that a state official believes he is making a "better" decision than the parent); *see also* *Wisconsin v. Yoder*, 406 U.S. 205, 235 (1972) (holding that Amish parents have a constitutional right based on freedom of religion and the fundamental right of parenting not to enroll their children in mainstream public schools).

203. *See* *Meyer v. Nebraska*, 262 U.S. 390, 403 (1923) (reversing the conviction of a schoolteacher who had violated a state law that prohibited instruction of foreign languages in Nebraska). The Court stated that the Nebraska Legislature "attempted materially to interfere with the calling of . . . teachers, with the opportunities of pupils to acquire knowledge, and with the power of parents to control the education of their own." *Id.* at 401.

204. *Id.* at 399.

205. *See* *Law*, *supra* note 84, at 1766 (stating that parents traditionally make medical decisions for their minor children until they come of age to make such important decisions for themselves).

206. *Moore*, 431 U.S. at 494.

207. *Parham v. J.R.*, 442 U.S. 584, 603 (1979).

208. *See* *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944) (noting that "[t]he right to practice religion freely [sic] does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death").

reasoning that its law was necessary, then the mandate will be upheld as constitutional.

Most states seek to mitigate the conflict between mandatory vaccination and parental rights by providing vaccination exemptions for certain individuals or for specific reasons.²⁰⁹ Although states are not constitutionally required to provide exemptions, most have chosen to do so.²¹⁰ All fifty states currently recognize medical exemptions from vaccinations for individuals who are likely to suffer to adverse effects from receiving the vaccine.²¹¹ Forty-eight states also provide religious exemptions for individuals demonstrating sincere religious convictions opposed to vaccination.²¹² Nineteen states currently provide exemptions for philosophical and personal convictions.²¹³ To take advantage of religious or philosophical exemptions, claimants must be opposed to vaccination in general, and not just to one vaccine in particular.²¹⁴

The Virginia Gardasil mandate contains a liberal exemption policy for parents. The provision has three sections, stating that a girl may be exempt from HPV vaccination, if:

1. The parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts

209. See Alicia Novak, *The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges*, 7 U. PA. J. CONST. L. 1101, 1107–08 (Apr. 2005) (explaining how states generally provide religious and philosophical exemptions).

210. See *id.* ("Currently, forty-seven states offer some form of religious exemption from school immunization laws... At least seventeen states allow philosophical exemptions...").

211. See Margaret J. Kochuba, Comment, *Public Health vs. Patient Rights: Reconciling Informed Consent with HPV Vaccination*, 58 EMORY L.J. 761, 783 (2009) (explaining that in every state, individuals claiming a medical exemption are required to present a written statement from a medical professional confirming their physical inability to be vaccinated).

212. *Id.* ("Forty-eight states also provide some sort of religious exemption, which may be utilized by individuals who are able to demonstrate sincerely held religious beliefs opposed to vaccination.")

213. See Sean Coletti, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1343 n.15 (2004) (stating that these states include Arizona, Arkansas, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, Texas, Utah, Vermont, Washington, and Wisconsin).

214. See *id.* at 1343 (noting that a religious exemption to Gardasil would place parents in a difficult position because claiming a religious exemption in these states would require foregoing vaccination for all vaccines, not just Gardasil).

with his religious tenets or practices, unless an emergency or epidemic of disease has been declared by the Board;²¹⁵

2. The parent or guardian presents a statement from a physician licensed to practice medicine in Virginia, or a licensed nurse practitioner, that states that the physical condition of the child is such that the administration of one or more of the required immunizing agents would be detrimental to the health of the child;²¹⁶
3. Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.²¹⁷

Under these three exemption provisions, parents can refrain from having their daughters vaccinated for a broad range of reasons; so long as their decision to forego vaccination is informed.²¹⁸

Virginia has a compelling governmental interest in promulgating its law because it is necessary to protect the public health from HPV's harmful and widespread effects. As detailed and discussed at length above, HPV affects a significant portion of the population,²¹⁹ and the State has an interest in protecting its schoolchildren from this harmful and potentially deadly virus.²²⁰ However, Virginia's current exemption provisions exhibit greater deference to parental rights than is appropriate, given the harmful effects of HPV. If a significant number of individuals are exempt, the public as a whole suffers because fewer people are vaccinated against this harmful and potentially deadly disease.²²¹ Therefore, the exemption provisions of Virginia's Gardasil mandate should be narrowed.

215. VA. CODE ANN. § 32.1-46(D)(1) (2009).

216. VA. CODE ANN. § 32.1-46(D)(2) (2009).

217. VA. CODE ANN. § 32.1-46(D)(3) (2009).

218. *See* Alcindor, *supra* note 3 (stating that parents need only read a form or speak to a medical professional about what they will be foregoing by refusing Gardasil administration for their child).

219. *See generally* *A Closer Look at Human Papillomavirus*, *supra* note 14 (providing statistics as to the prevalence of HPV throughout the population).

220. *Id.*

221. *See generally* Skov, *supra* note 130, at 816–17 (explaining the effects of nonvaccination upon herd immunity).

Parents opposed to the Virginia Gardasil mandate argue that the law usurps their constitutionally protected rights to raise their children in the way that they see fit.²²² They argue that Virginia needs a more compelling reason to mandate Gardasil in the face of their parental rights besides the state's belief that it is making a "better" decision regarding their daughter's health.²²³ They argue that because the government should not interfere with their parental autonomy, they should qualify for an exemption for virtually any reason, including religion,²²⁴ philosophical and moral opposition to vaccination,²²⁵ health reasons,²²⁶ and general opposition to Gardasil vaccination for their daughters.²²⁷

Although these parental arguments raise legitimate concerns, the government has the constitutional right to supersede individual parental rights and require vaccination in this case because HPV is significantly harmful to children and has devastating effects on the Virginia population at large.²²⁸ Countless lives could be saved and other serious health consequences avoided if Virginia's Gardasil law was mandatory with narrower exemptions.²²⁹ Gardasil would be more readily available to racial minorities, the uninsured, and low-income individuals.²³⁰ As Rebecca E. Skov of The Food and Drug Law Institute states: "the effect of immunizing

222. See Gendel, *supra* note 8, at 284–88 (arguing that parental rights are infringed upon by mandating HPV vaccination in public schools); see also Skov, *supra* note 130, at 822–23 (discussing parental acceptance and opposition to Gardasil vaccination mandates as a prerequisite to schooling); see also Kochuba, *supra* note 211, at 785–87 (arguing that mandatory HPV vaccine programs undermine patient rights).

223. See Gendel, *supra* note 8, at 284 (quoting *Troxel v. Granville*, 530 U.S. 57, 68–69 (2000)).

224. See generally Novak, *supra* note 209 (arguing that the overuse of various religious and philosophical exemptions from school-mandated vaccinations is problematic).

225. See *id.* at 1117 (detailing constitutional arguments raised regarding philosophical exemptions from child vaccination requirements).

226. See *id.* at 1121–22 (discussing potential health risks justifying mandatory vaccinations).

227. See *id.* at 1118–28 (discussing various reasons parents opt out of child vaccinations, including the rights of their unvaccinated children, health risk concerns, improper regulation of vaccine side effects, and societal concerns).

228. See Javitt et al., *supra* note 16, at 385 (stating that up to eighty percent of the sexually active female population will have the virus at some point before age fifty).

229. See Law, *supra* note 84, at 1768–70 (describing the benefits of mandatory HPV vaccination law on society collectively, including prevention of harmful and deadly diseases, promotion of herd immunity, and more availability of vaccines for uninsured, poor, and minority women).

230. See *id.* (explaining the benefits of the mandate for uninsured, poor and minority women).

[even] one generation of schoolchildren [from HPV] could be a monumental success against cervical cancer as well as against a persistent and sometimes embarrassing sexually transmitted infection, genital warts."²³¹

The government's argument for overriding parental objections and requiring Gardasil vaccination is deeply rooted in Supreme Court precedent. In *Prince v. Massachusetts*,²³² the Supreme Court analyzed a child labor law and found that "the State has a wide range of power for limiting parental freedom and authority in things affecting the child's welfare; and that this includes, to some extent, matters of conscience and religious conviction."²³³ In *Wisconsin v. Yoder*,²³⁴ the Court reaffirmed in dicta its readiness to abrogate parental rights when they endanger the well-being of minors.²³⁵ In 1990, *Employment Division Department of Human*

231. Skov, *supra* note 130, at 818.

232. See *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944) (establishing that "the right to practice religion freely [sic] does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death"). In *Prince*, the Court considered whether state child labor laws infringed upon freedom of religion and denied equal protection. *Id.* at 159–60. The appellant, Sarah Prince, was convicted of violating state child labor laws by requiring her nine-year-old niece to sell magazines on the street. *Id.* at 160. Prince claimed her niece distributed magazines in accordance with the doctrines believed by Jehovah's Witnesses. *Id.* at 161–62. The Court determined that while parents are free to teach children religious doctrines, they are not above regulations intended to protect youth. *Id.* at 165–66.

233. *Id.* at 167.

234. See *Wisconsin v. Yoder*, 406 U.S. 205, 214–19 (1972) (concluding that Amish children did not need to attend mainstream public schools because these parental objections were based on religious, and not distinctive cultural, beliefs). In *Yoder*, the Court considered whether objections to a state's compulsory school attendance law violated the respondents' constitutionally protected right to freedom of religious practice. *Id.* at 207. The Court determined that the traditional Amish way of life adhered to by the respondents was in direct conflict with the principles taught through public schools after eighth grade. *Id.* at 209–11. Reasoning that the State's interest in education must be balanced against the potential harm to fundamental rights, the Court found that the Amish way of life was fundamentally coexistent with their religious beliefs. *Id.* at 214–18. As such, the compulsory attendance law infringed upon the respondents' right to free exercise of religion. *Id.* at 219. The Court considered numerous factors in arriving at its unusual decision, including whether the practice was a shared belief by an organized group rather than a personal experience; whether the system of Amish beliefs pervaded and regulated the daily lives of the Amish; and whether the system of belief and the resultant lifestyle had existed for a substantial period of time. *Id.* at 216–17.

235. See *id.* at 214 (finding that "a State's interest in universal education, however highly we rank it, is not totally free from a balancing process when it impinges on fundamental rights and interests, such as . . . the traditional interest of parents with respect to the religious upbringing of their children").

*Resources v. Smith*²³⁶ recognized that an individual's religious beliefs do not excuse him from adhering to a valid state law of general applicability.²³⁷ The Court further expanded the notion that parental rights may give way to state interests in *Planned Parenthood of Central Missouri v. Danforth*,²³⁸ and *Parham v. J.R.*²³⁹ In *Danforth*, the Court held unconstitutional a state statute granting parents an absolute veto over a minor's decision to have an abortion.²⁴⁰ In *Parham*, a group of minors sought relief from a Georgia law allowing parents to voluntarily commit children to mental institutions.²⁴¹

236. See *Employment Div., Dep't of Human Res. v. Smith*, 494 U.S. 872, 890 (1990) (upholding a neutral state law banning the use of peyote without recognizing any constitutional exception for religious use based on the Free Exercise Clause). In *Smith*, the Court considered whether an Oregon state law prohibiting the use of peyote violated First Amendment rights to freedom of religion. *Id.* at 874–76. The respondents were fired from their jobs after ingesting peyote during a religious ceremony through the Native American Church. *Id.* at 874. Existing case law supported the contention "that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate." *Id.* at 878–79. When the conduct prohibited is not related to freedom of speech or the right of parents to make decisions for their children, religious beliefs cannot overcome a valid law. *Id.* at 882.

237. *Id.* at 878–79.

238. See *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 71–84 (1976) (invalidating most of the restrictions set forth in a Missouri statute that limited a woman's access to an abortion). In *Danforth*, the Court considered the constitutionality of restrictions placed upon access to abortion within Missouri. *Id.* at 55–58. The plaintiffs challenge the restriction limiting abortions based upon "viability," a term defined by the state legislature as being twelve weeks after conception, and the required consent of the woman's spouse or parent. *Id.* at 58. Additionally, the plaintiffs challenged the provision requiring physicians to "exercise professional care 'to preserve the life and health of the fetus'" or to face manslaughter charges. *Id.* The Court found that it was unconstitutional for a state to require the consent of a spouse or parent. *Id.* at 68–74.

239. See *Parham v. J.R.*, 442 U.S. 584, 620–21 (1979) (upholding Georgia's procedures for voluntary civil commitment of children by their parents). In *Parham*, the Court considered whether a child's due process rights were violated under a Georgia statute allowing a parent to civilly commit a child. *Id.* at 587. The Court balanced a number of considerations in making its determination, including the affected private interest, the risk of "erroneous deprivation," the "probable value, if any, of additional or substitute procedural safeguards," and the administrative costs of such procedures. *Id.* at 599–600. The Court upheld the statute and found the process adopted by Georgia to be "reasonable and consistent with constitutional guarantees." *Id.* at 620.

240. See *Danforth*, 428 U.S. at 73–74 (holding that Missouri cannot impose a blanket parental consent requirement as a condition for an unmarried minor's abortion in an attempt to safeguard the family unit and parental authority). The *Danforth* Court relied on *Roe v. Wade*, 410 U.S. 113, 163 (1973) to find that the abortion decision must be left up to the woman and the medical judgment of her attending physician. *Id.* at 61.

241. See *Parham*, 442 U.S. at 590–91 (describing that under the Georgia statute, the application for voluntary hospitalization required a signature from a parent or guardian).

The *Parham* Court stated that, "parents do not always have absolute discretion to institutionalize a child; they retain plenary authority to seek such care for their children subject to an independent medical judgment."²⁴² Therefore, if the Supreme Court has found that states can enforce labor, education, and health laws over parental objections, it would be reasonable to conclude that Virginia can enforce a life-saving vaccine to protect children.

Many state courts have applied the above Supreme Court precedent and reasoning in various situations, including compulsory vaccination,²⁴³ genetic testing,²⁴⁴ chemotherapy treatments,²⁴⁵ and other necessary medical procedures.²⁴⁶ Most interestingly, in *In re J.J.*²⁴⁷ the Court of Appeals for the Twelfth District of Ohio ordered parents to treat their fourteen-year-old

The hospital superintendent was authorized to temporarily admit any child for observation and diagnosis if there was evidence of mental illness, and the child could be admitted "for such period and under such conditions as may be authorized by law." *Id.* at 591. Under the statute, any child hospitalized for more than five days could be discharged at the request of a parent or guardian. *Id.*

242. *Id.* at 585.

243. *See, e.g.,* Scherr v. Northport-East Northport Union Free Sch. Dist., 672 F. Supp. 81, 94 (E.D.N.Y. 1987) (declining to waive vaccination requirements for child whose Christian Scientology religious beliefs were not "sincerely held"); *see also* Farina v. Bd. of Educ. of N.Y., 116 F. Supp. 2d 503, 507 (S.D.N.Y. 2000) (holding that a religious exemption only exempts those whose opposition extends from religion, not "medical or purely moral considerations"); *see also* Staffel v. San Antonio Sch. Bd. of Educ., 201 S.W. 413, 414 (Tex. App. 1918) (overriding a parental objection to vaccination for religious reasoning); *see also* McCarthy v. Boozman, 212 F. Supp. 2d 945, 949 (W.D. Ark 2002) (holding that pursuant to a state's police power, Arkansas could adopt a compulsory vaccination program for schoolchildren without providing a religious exemption).

244. *See In re Willman*, 493 N.E.2d 1380, 1390 (Ohio Ct. App. 1986) (ordering parents to obtain chemotherapy treatment for their sick child, despite their Christian Scientology religious belief opposing medical treatment).

245. *See Tennessee v. Hamilton*, 657 S.W.2d 425, 429 (Tenn. Ct. App. 1983) (ordering chemotherapy for a child that was unlikely to save her life, but would alleviate her pain and suffering, despite her parents' religious opposition to the chemotherapy treatment).

246. *See, e.g.,* Muhlenberg Hosp. v. Patterson, 320 A.2d 518, 521 (N.J. Super. Ct. Law Div. 1974) (ordering a blood transfusion for a jaundiced infant whose parents were religiously opposed to such procedures because they were Jehovah's Witnesses).

247. *See In re J.J.*, 582 N.E.2d 1138, 1140-41 (Ohio Ct. App. 1990) (per curiam) (holding that parents of a fourteen-year-old child were required to get their son treatment for gonorrhea because he continued to be a risk to his classmates because he remained sexually active). After being diagnosed with acute gonorrhea, J.J., a minor child, refused medical treatment as being against his religious beliefs. *Id.* at 1139. The court determined it was within the State's rights to set age limitations on certain activities and behaviors. *Id.* at 1140-41. The court found J.J.'s highly contagious disease and the fact that he remained sexually active were sufficient grounds to require him to receive treatment. *Id.* at 1140.

son's sexually transmitted disease.²⁴⁸ The boy had contracted gonorrhea and his parents refused treatment, despite the fact that he continued to be sexually active.²⁴⁹ The court reasoned that without necessary treatment the boy continued to place his classmates at risk, and therefore required him to undergo treatment.²⁵⁰ *In re J.J.* is instructive because of its parallels to HPV Gardasil vaccination laws.²⁵¹ Both the Ohio General Assembly in *In re J.J.* and the Virginia General Assembly are attempting to stop the spread of an easily communicable sexually transmitted disease.²⁵² Without treatment or proper preventive measures, classmates in both situations are at risk for contracting the disease.²⁵³ Following the reasoning of *In re J.J.*, the law mandating Gardasil for schoolchildren would appear to be justifiable.

Allowing exemptions from Virginia's Gardasil mandate due to parental objections also hinders "herd immunity" from HPV.²⁵⁴ According to the herd immunity theory, a population becomes immunized to a disease over time because viable disease transmitters are eliminated, and the population as a whole benefits because the likelihood of the spread of infection decreases.²⁵⁵ The "no shots, no school" policy is a highly effective and cost efficient way to achieve this result.²⁵⁶ The effectiveness of school-based vaccination mandates can be inferred from a natural experiment that occurred in Texarkana, Texas, in 1970.²⁵⁷ Texarkana is

248. *Id.* at 1141.

249. *Id.* at 1139–41.

250. *Id.* at 1141.

251. *See* Gendel, *supra* note 8, at 286 (providing a comparison between mandating treatment for a sexually transmitted disease in *In re J.J.* and HPV vaccination laws, which both involve an easily communicable sexual infection placing classmates at risk).

252. *Id.*

253. *Id.*

254. *See* Skov, *supra* note 130, at 816–17 ("[A]llowing individuals to exercise autonomy [in the form of conscientious/religious objections] is in conflict with the principle of herd immunity.").

255. *See* Globerson, *supra* note 7, at 255–56 (discussing the herd immunity justification for mandating the Gardasil vaccine); *see also* Jane J. Kim & Sue J. Goldie, Health and Economic Implications of HPV Vaccination in the United States, 359 *NEW ENG. J. MED.* 821, 827–29 (2008) (describing the medical and economic benefits of herd immunity from HPV and noting that when girls receive the vaccine early in their lives, the attainment of herd immunity is more likely).

256. *See* Law, *supra* note 84, at 1745–47 (describing how school-based vaccinations are a highly efficient and cost effective method of significantly reducing communicable diseases in the United States).

257. *See id.* at 1746 (describing the natural experiment that took place in Texarkana, Texas in 1970 in regard to a measles outbreak).

located on the state border between Texas and Arkansas. At that time, measles vaccination was not required in Texas, but was in neighboring Arkansas.²⁵⁸ When an epidemic broke out, the rate of infection was more than twelve times higher in Texarkana than in Arkansas.²⁵⁹ Because the two areas were so closely related geographically, one would expect the rate of infection in the two populations to be roughly equivalent. The vaccine requirement constituted the only significant difference between the two neighboring populations.²⁶⁰ As a result, Texarkana experienced a significantly higher infection rate than Arkansas because the State of Texas lacked a vaccination mandate against measles. Shortly after the measles outbreak, Texas mandated the vaccine for school attendance, and the Texas Supreme Court affirmed the law in 1973.²⁶¹

The availability and number of exemptions a state allows directly affect the level of vaccination and disease reduction across a state's population as a whole.²⁶² The more exemptions available to citizens, the more these citizens will choose to opt out of being vaccinated.²⁶³ The end result is that the vaccine is less efficient in eradicating the disease it was designed to combat in the first place.²⁶⁴ In *Human Papillomavirus Vaccination, Private Choice, and Public Health*, Sylvia Law points out that "[w]hen exemptions are broad and freely given, diseases that can be prevented through vaccination re-emerge."²⁶⁵ Bacteria and viruses causing harmful and deadly diseases linger in individuals refusing to be vaccinated, and will reappear to infect future generations.²⁶⁶ Essentially, as the rate of state exemptions increases, the efficacy of vaccination decreases statewide.²⁶⁷

As indicated above, the Virginia General Assembly has compelling reasons to supersede parental rights in enforcing its necessary Gardasil

258. *Id.*

259. *Id.*

260. *Id.*

261. *Id.*

262. See Skov, *supra* note 130, at 816 (describing the effects on herd immunity, noting that "[e]xemptions from mandatory public health measures can be problematic").

263. *Id.*

264. *Id.*

265. Law, *supra* note 84, at 1769.

266. See Skov, *supra* note 130, at 816 (describing how refusal to be vaccinated impacts herd immunity rates).

267. See Law, *supra* note 84, at 1769 ("As a practical matter, the availability of exemptions affects the level of vaccination [statewide].").

mandate for schoolchildren. However, narrower exemptions from the law should be created because HPV will continue to spread if an effort is not made to curb it. The most effective approach the Virginia General Assembly can take is to mandate Gardasil and narrow the exemption provisions to allow only for specific medical objections. To qualify for these medical exemptions, parents would be required do more than merely check a box on a form indicating that they object to Gardasil for medical purposes. Rather, the Commonwealth should require parents to provide a short written statement stating why their children are medically unable or unwilling to be vaccinated. Parents should attach written documentation from a medical professional or physician validating the stated medical reason for the exemption. This information should then be relayed to Virginia public health officials in order to determine if the stated reason indeed qualifies for an exemption. Children should not be denied protection from HPV because of their parents' philosophical, conscientious, scientific, political or personal beliefs. These types of exemptions should not be allowed because it is too difficult to distinguish between parents with sincere objections, and free riders to the exemption provisions who are too lazy to have their child's physician fill out a vaccination form. In order for immunization laws to be effective and for herd immunity to be achieved, these lax exemptions must be narrowed to ensure safety and protection of the public health. After all, "[i]t is the State's duty under the police powers to protect the health, safety, and welfare of the populous."²⁶⁸ If Virginia requires more than merely checking a box on a form, it can ensure the exemption is sincere.

III. Gardasil: Selective or Equal Protection?

On October 16, 2009, the FDA approved Gardasil for males.²⁶⁹ Each year, two out of every one thousand men in the United States are diagnosed with anogenital warts.²⁷⁰ More importantly, requiring men to receive Gardasil can significantly reduce chances of HPV transmission to a sexual partner.²⁷¹ Men serve as carriers of the HPV strains linked to cervical

268. Skov, *supra* note 130, at 820.

269. See FDA News Release, *supra* note 7 (announcing FDA approval for Gardasil use in boys and men, ages nine through twenty-six).

270. *Id.*

271. See Medical News Today, *Wall Street Journal Examines Potential Use of Gardasil Among Young Men*, Feb. 5, 2009, available at <http://www.medicalnewstoday.com>.

cancer.²⁷² HPV is also associated with several cancers affecting only men, including penile cancer.²⁷³ Urethral, anal, oral, and throat cancers caused by HPV equally affect men and women.²⁷⁴ In fact, a recent study conducted by Johns Hopkins University and The National Cancer Institute found that HPV-associated oral carcinoma occurs more frequently in men than women.²⁷⁵

Vaccinating young men against HPV also significantly benefits herd immunity, resulting in more than ninety percent of HPV cases caused by the four most common strains to be eradicated.²⁷⁶ If half the relevant population infected with HPV is exempt from Gardasil, the hope of achieving herd immunity will never fully be realized.²⁷⁷ Dr. Anne Szarewski, a British physician and clinical consultant at Cancer Research UK, argues that: "vaccinating only girls is a shortsighted and potentially damaging strategy . . . Vaccinating only women reinforces the idea that sexual health is solely a female concern and that nice girls are not at risk."²⁷⁸

Immunization of all adolescents with Gardasil is necessary for effective and long-term HPV eradication.²⁷⁹ The vaccine should be

com/articles/137943.php (stating that HPV is easily transmitted sexually) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

272. *See id.* (describing the medical and societal effects Gardasil would have on the population as a whole if it were to become available for males as well).

273. *See id.* (stating that HPV-related penile cancer is a risk factor in men).

274. *See id.* (stating that different types of cancers commonly linked to HPV affect both men and women); *see also* Samuel Broder, M.D., *Why Isn't There a Gardasil for Men?*, U.S. NEWS & WORLD REP., May 18, 2009, available at <http://health.usnews.com/health-news/blogs/health-advice/2009/05/18/why-isnt-there-a-gardasil-for-men> (stating that Gardasil is beneficial to both men and women since both sexes suffer from certain types of cancers that are commonly linked to HPV) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

275. *See* Broder, *supra* note 274 (describing the results of a recent study conducted by Johns Hopkins University and The National Cancer Institute, in which it was shown that HPV-related oral cancer occurs more frequently in men than women). The study suggested that HPV-associated oral cancer is associated with more than twenty-five lifetime sex partners and more than six lifetime oral sex partners. *Id.*

276. *See* Kristin Cook, *Ethical and Legal Issues Accompanying Legislation Requiring HPV Vaccination of Girls*, 18 HEALTH MATRIX 209, 227 (2008) (discussing the benefits of requiring vaccinating men with Gardasil).

277. *See* Law, *supra* note 84, at 1761 (stating that in order to fully achieve and benefit from herd immunity, men should be vaccinated with Gardasil as well).

278. *See* Nicki Daniels, *Boys Should Be Vaccinated Too*, TIMES (U.K.), Oct. 27, 2006 (quoting Dr. Anne Szarewski).

279. *See* Law, *supra* note 84, at 1761–62 (finding that immunizations of boys with Gardasil will significantly benefit herd immunity, thus proving successful for long-term

mandatory for both boys and girls in Virginia public schools because the FDA and CDC have now approved Gardasil for men. Unless boys are included under the Virginia law, Virginia will be in violation of the Equal Protection Clause of the Fourteenth Amendment.²⁸⁰

A. The Virginia Law As It Stands Violates the Equal Protection Clause

The Fourteenth Amendment states that no person shall be denied "equal protection of the laws."²⁸¹ In applying the Equal Protection Clause to gender discrimination cases, the Supreme Court has held that "classifications by gender must serve important governmental objectives and must be substantially related to the achievement of those objectives."²⁸² When a law or policy includes differing gender standards, the government must provide an "exceedingly persuasive justification" for its actions.²⁸³ Gender-based classifications may recognize physical and organic differences between males and females, but must not be based upon misleading generalizations or gender-based stereotypes.²⁸⁴

eradication of HPV).

280. An argument could also be made that Virginia's Gardasil mandate for school girls violates Title IX of the Education Amendments of 1972, which state that "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." Title IX applies to all public and private educational institutions that receive federal funds. Since nearly all elementary schools in Virginia receive some degree of federal funding, female students and their parents could claim the Virginia law as it stands violates Title IX because it denies girls participation in school based on their gender. Because the issue of a single-sex vaccine is so recent, there is currently no reported caselaw analyzing such an issue. However, since Gardasil has recently been approved for men, courts would be hard-pressed to find that any law requiring female-only vaccination as a precondition to schooling when the vaccine is also available for men would not constitute a Title IX violation. Therefore, unless the Virginia General Assembly amends VA. CODE ANN. § 32.1-46 to require Gardasil vaccination for both females and males, it could likely face Title IX challenges in addition to already existing claims of equal protection violations.

281. U.S. CONST. amend. XIV, § 1.

282. *Craig v. Boren*, 429 U.S. 190, 197 (1976).

283. *See United States v. Virginia*, 518 U.S. 515, 534 (1996) (quoting *J.E.B. v. Ala.*, 511 U.S. 127, 136-37 (1994) and *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1992)).

284. *See Michael M. v. Super. Ct. of Sonoma County*, 450 U.S. 464, 469 (1981) (finding that the Court has routinely upheld statutes where gender-based classifications reflect inherent differences between the sexes). In this case, the Court upheld a state rape law imposing criminal liability on males who had sex with females under the age of eighteen; but not on females having sex with underage males. *Id.* at 472-74. *See also*

Two seminal cases established the constitutional standard for evaluating equal protection claims based on gender discrimination. In *Craig v. Boren*,²⁸⁵ an Oklahoma statute prohibiting the sale of beer to men under twenty-one and women under eighteen was challenged as unconstitutional.²⁸⁶ The male plaintiffs claimed the statute discriminated against males between the ages of eighteen and twenty because it permitted females in the same age range to buy beer.²⁸⁷ In response, the government asserted Oklahoma's sex-based classification served the important governmental objective of preventing drunk driving, because statistics indicated that males between the ages of eighteen and twenty were the most likely to drive drunk.²⁸⁸ The Supreme Court found gender was not a legitimate proxy for regulating drunk driving, and that the government's asserted reasoning therefore did not constitute an important governmental objective.²⁸⁹ The Court struck down the statute as an equal protection violation based on gender discrimination.²⁹⁰

In *United States v. Virginia*,²⁹¹ the Supreme Court further shaped its gender classification legal framework when it addressed whether denying

Rostker v. Goldberg, 453 U.S. 57, 83 (1981) (upholding Congress' exclusion of women from registration for the draft); *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 733 (1982) (striking down a statute excluding males from enrolling in state-supported nursing schools because this was traditionally classified as a female profession); *United States v. Virginia*, 518 U.S. at 516 (stating that sex-based classifications cannot rely on overly broad generalizations and stereotypes about "different talents, capacities, or preferences of males and females").

285. See *Craig v. Boren*, 429 U.S. 190, 210 (1976) (striking down an Oklahoma statute prohibiting the sale of 3.2 percent beer to males under the age of twenty-one and to females under the age of eighteen). The Court applied a middle tier standard of review, noting that a gender classification must serve important governmental objectives and must be substantially related to achievement of those objectives. *Id.* at 211.

286. *Id.* at 192.

287. *Id.*

288. See *id.* at 200 (explaining that the state introduced a variety of statistical surveys designed to show that arrest and accident rates involving alcohol were far greater for males in the eighteen to twenty-one age range than their female counterparts). This information asserted that actions should be taken to advance the health and safety of the public from drunk drivers. *Id.*

289. See *Craig v. Boren*, 429 U.S. 190, 204 (1976) (finding that although the protection of public health and safety represented an important function of state and local governments, that objective did not justify the classification because it did not appear on the face of the statute or in any recorded legislative history).

290. See *id.* at 209 (noting that the Court was reluctant to allow statistics to justify what it believed to be blatant gender discrimination).

291. See *United States v. Virginia*, 518 U.S. 515, 535 (1996) (holding that The Virginia Military Institute's all-male policy violated the Equal Protection Clause because it denied

women admission to a publicly funded university, Virginia Military Institute (VMI), constituted an equal protection violation.²⁹² Virginia claimed that admitting women would "downgrade VMI's stature, destroy the adversative system, and, with it, even the school."²⁹³ The Court found this reliance on overly broad generalized differences between the sexes did not provide an exceedingly persuasive justification for its discriminatory policy and ordered VMI to admit female students because "the Constitution's equal protection guarantee precludes Virginia from reserving exclusively to men the unique educational opportunities VMI affords."²⁹⁴ *Virginia* established that in order for a sex-based classification to survive intermediate scrutiny, the classification must exhibit an "exceedingly persuasive justification" for the means chosen to further the state's important objective.²⁹⁵

As the Virginia Gardasil law presently stands, it requires only that all female students entering the sixth grade be vaccinated with Gardasil.²⁹⁶ Similar to the policies in *Craig* and *Virginia*, this law constitutes an equal protection violation because the vaccine is now available for males as well. In order to survive intermediate scrutiny, the Virginia law must be *substantially related* to an *important* government objective (emphasis added).²⁹⁷ The government certainly has an important objective in its current version—preventing HPV and cervical cancer. Furthermore, without requiring males to be immunized as well, herd immunity from HPV

women who were capable of the same activities as their male applicant counterparts the unique VMI educational opportunity). A female applicant denied admission argued that Virginia Military Institute's all-male policy violated equal protection of the law and was therefore unconstitutional. *Id.* at 523. The Court found there the State did not provide an "exceedingly persuasive" argument in support of the policy. *Id.* at 545. The policy was struck down as unconstitutional because the State failed to meet its burden. *Id.* at 556–59.

292. *See id.* at 523 (stating that a female applicant brought suit against VMI when she was denied opportunity for admission based on her gender).

293. *Id.* at 542.

294. *Id.* at 519.

295. *See United States v. Virginia*, 518 U.S. 515, 523 (1996) (noting that a state must at least show the challenged classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives).

296. To date, the Virginia General Assembly has not offered any reason why the law continues to only be required for females entering the sixth grade in Virginia.

297. *See United States v. Virginia*, 518 U.S. at 524 (finding that gender-based classifications must advance "important governmental objectives" and the classification must "substantially relate to the achievement of those objectives"); *see also Craig v. Boren*, 429 U.S. 190, 197 (1976) (same).

will never be achieved.²⁹⁸ Even though the law is substantially related to this important objective, it is still discriminatory and unfairly burdens women. Thus, it is unlikely to survive intermediate scrutiny analysis. The Virginia General Assembly should amend the law to require *all* girls *and* boys entering the sixth grade to be vaccinated with Gardasil in order to avoid an equal protection violation.

IV. Conclusion and Proposal to the Virginia General Assembly

HPV is a dangerous and potentially deadly virus that has significantly infiltrated the American public. It is easily transmittable and often produces no noticeable signs and symptoms, thus making the virus even more difficult to control. An attempt must be made to stop HPV's rapid spread throughout the population. To date, the best method of prevention is the Gardasil vaccine. Gardasil is a revolutionary vaccine that has the potential to drastically reduce cervical cancer rates, the second leading cause of cancer deaths in women, and anogenital warts.

The Commonwealth of Virginia has a duty to protect the public from the harmful effects of HPV. An effective means of achieving this goal is by vaccinating young generations before they begin to have sex so as to eradicate the virus from the population over time. High immunization levels directly benefit the public health through herd immunity. Therefore, the Virginia General Assembly has a compelling reason to mandate that all schoolchildren receive Gardasil, along with their other necessary vaccinations, prior to starting the sixth grade. The research in this Note supports the proposition that the mandate is a proper use of Virginia's police power under the Tenth Amendment and does not violate substantive due process concerns under the Fourteenth Amendment relating to bodily privacy and unwanted bodily intrusion, because Virginia has necessary and compelling reasoning for enforcing its law.

To ensure that the mandate is effective in inhibiting and eventually eradicating HPV from the population, the Virginia General Assembly should narrow the law's exemption provisions to allow only for compelling medical exemptions. To qualify for these medical exemptions, parents should provide a short written statement stating why their child is medically unable to receive Gardasil. Parents should attach written documentation from a physician validating their asserted reason for the exemption. This

298. See Skov, *supra* note 130, at 816–17 (explaining that herd immunity is negatively affected by nonvaccination within the population).

information should then be relayed to Virginia public health officials to determine if the child indeed qualifies for the exemption. Promoting HPV vaccination is essential to the public health, and therefore the government should be selective in granting exemptions.

Given HPV's high prevalence and harmful effects, the Virginia General Assembly can supersede parental objections to vaccination when enforcing this law. As is evidenced by the research featured in this Note, courts have traditionally chosen to protect the public health over individual interests. If one compares the unsupported risks of supposed promiscuity at a young age with the benefit of potentially eradicating anogenital warts and drastically reducing cervical cancer later in life, it is evident that logic favors mandating vaccination.

Lastly, the Virginia General Assembly should amend the law to also require HPV vaccination of male students because Gardasil is now available for males as well. If the law is not amended, it will likely be found that the government is discriminating on the basis of gender and violating the Equal Protection Clause.

As a result of Virginia's Gardasil mandate, the population as a whole will benefit and the public health will be protected from HPV. Hopefully, the proposals set forth in this Note will provide a starting point toward enforcing a constitutionally sound law that will benefit the greater good.