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Do the Ends Justify the Means? Compelling the Use of HPV Vaccination on Men

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In recent years, the human papillomavirus (HPV) has become a focal point in the media for its effects in young women. HPV is a sexually transmitted infection (STI), which can cause cervical cancer in women and has infected close to twenty million people. However, men are mere carriers of the virus. In 2006, pharmaceutical producer Merck and Co., Inc.

1. See Genital HPV Infection - Fact Sheet, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/std/HPV/STDFact-HPV.htm (last visited Oct. 30, 2010) [hereinafter HPV Fact Sheet]. HPV is a virus that contains more than forty different types. It can infect the genital areas of men and women, including the skin of the penis, vulva (area outside the vagina), anus, and the linings of the vagina. Id.

2. See generally Bridget J. Kelly, The HPV Vaccine and the Media: How Has the Topic Been Covered and What are the Effects on Knowledge About the Virus and Cervical Cancer?, 77 PATIENT EDU. AND COUNSELING 308 (2008). Kelly discusses how the media has covered the HPV vaccine and how the vaccine was affected by such coverage. She concludes that media coverage greatly increased after the vaccine was introduced in 2006; however, an analysis of the coverage reveals that many stories were incomplete. Id. See generally Abnormal Pap Smears, HPV, CIN, VIN and VAIN, GYNECOLOGIC ONCOLOGY ASSOCs., http://franklin.liquidweb.com/~gynoncol/physicians/mrk-a-rettermaier-md/personal-observations/abnormal-pap/ (last visited Nov. 7, 2010).

3. See HPV Fact Sheet, supra note 1.

introduced Gardasil®, a vaccine that, when given to adolescent girls before they become sexually active, can prevent HPV. The introduction of the vaccine prompted major medical, moral and legal debates. While doctors debated the safety and efficacy of the vaccine, religious leaders debated the potential promiscuity that the availability of the vaccine might encourage. At the state level, some politicians introduced legislation that would require girls to be vaccinated for school enrollment; only two such efforts have become law.

The debate recently expanded to include discussion of vaccinating men. In 2009, the Food and Drug Administration (FDA) approved the HPV vaccine for use in men. This controversial approval initiated heated debate on public policy, economic, and health grounds for expanding vaccination to men. Although all states have mandatory vaccination laws for school enrollment, historically such requirements have sought to protect against

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communicable diseases such as polio, rubella and the measles. In addition, such laws must meet the constitutional standards set forth by the United States Supreme Court in Jacobson v. Massachusetts. Because mandatory vaccination laws have been successful in the past, it would seem logical that lawmakers would start introducing laws compelling the HPV vaccine on men as well as women, as a strategy for protecting against the virus. Currently, no state has introduced such legislation compelling vaccination on men. This Note will argue that mandatory HPV vaccination in men would allow for impermissible government intervention into privacy rights; that the HPV vaccine has not been studied enough to show long-term safety or efficacy; and that vaccinating men against HPV is not cost-effective. It has been argued elsewhere that the Jacobson test needs updating, but this Note accepts the Jacobson five-prong test and argues that the government should not require men to purchase an expensive vaccine that does little to protect the public at large. This Note examines the arguments that could be made in support and in opposition of mandating the vaccine in men using similar arguments already made in reference to the vaccination of women.

This Note will open with a full discussion of HPV, its connection to cervical cancer, and its relation to men. Part III will address the historical and legal reasons for compelling vaccination. The next section will discuss the HPV vaccine and its recent approval for men. Part V will examine the debate regarding the HPV vaccine's safety and efficacy, while outlining the extreme cost of the vaccine and questioning whether it is cost effective to compel men to be vaccinated. Part VI of this Note addresses privacy rights and the implications of compelling vaccination. Part VII analyzes the constitutionality of compelling vaccination, in light of the test set forth in


13. See generally Benjamin Lemke, Why Mandatory Vaccination of Males Against HPV is Unconstitutional: Offering a New Approach to an Old Problem, 19 B. U. Pub. Int. L. J. 261 (2010). Lemke argues that as more vaccinations are developed that do not address pressing needs, the test into whether mandatory vaccinations are constitutional as laid out in Jacobson v. Massachusetts needs updating. He presents a new "Modified Hand Formula," a test that balances the key competing concerns inherent in any discussion of the constitutionality of mandatory vaccinations. Id. at 261. This Note differs in that it accepts the Jacobson test and discusses the prongs of the test, the efficacy and safety of the vaccine, and the economic considerations.
**Jacobson v. Massachusetts.** This section also analyzes the HPV vaccine under the *Jacobson* factors and determines that mandating the HPV vaccination in men would likely be held unconstitutional. Part VIII discusses the burden an expensive vaccine would have on our health care system and the compulsory vaccination legislation that has been introduced at the state level. This Note concludes that the government should not compel men to purchase an expensive vaccine that does little to protect the public at large when, it is not cost-effective, the safety and efficacy are questionable, and such action impinges on privacy rights.

**II. INTRODUCING HPV**

The Centers for Disease Control and Prevention (CDC) reports that HPV is the most common STI. An estimated twenty million Americans are currently infected with HPV, yet most are unaware. According to Dr. Eileen Dunne from the CDC, one of the leading researchers on HPV and its vaccine, “there’s a lot of misunderstanding about HPV’s complex natural history. It’s not that if you get the infection, you get the disease. It is a common infection, and a lot of them clear [on their own].” The CDC reports that at least fifty percent of sexually active men and women become infected with HPV at some point in their lives. While most cases clear up without the infected individual ever knowing he was infected, some cases develop into more serious conditions.

There are more than one hundred strains of the virus, but only fifteen are categorized as “high risk” because of their association with cervical cancer, the eleventh most common cancer in women. “Low risk” strains are

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14. *HPV Fact Sheet, supra note 1*, at 1.

15. *Id.* at 2. According to the CDC, in ninety percent of cases, a person’s immune system will clear the infection without the infection’s manifesting any symptoms. *Id.* at 1.

16. *See id.*


18. *HPV Fact Sheet, supra note 1*, at 2.


20. *Id.; see also Dowling, supra note 4, at 72; see also AM. SOC. HEALTH ASS’N, FREQUENTLY ASKED QUESTIONS ABOUT CERVICAL CANCER/HPV VACCINE ACCESS IN THE*
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classified as such when they lead to genital warts in both men and women. In 2006, HPV caused cervical cancer in approximately 10,000 American women, resulting in 3,700 deaths. Comparatively, these numbers are drastically higher worldwide. Although the CDC estimates very high numbers of infected people, independent studies by Lisa Manhart and Dr. Dunne conclude that the prevalence of HPV in women is around twenty-six percent, which is much lower than CDC estimates. These studies also question the effectiveness of current prevention and treatment options, including the HPV vaccine.

III. THE PATH TO MANDATORY VACCINATION IN THE UNITED STATES

The historical development of vaccinations is an integral part of this discussion because it reflects the balancing act American policymakers must achieve to protect privacy rights while simultaneously looking out for the interests of the state. As early as the seventeenth century, when the first reported vaccinations were used in India and China, researchers developed vaccines as part of an effort to protect the public from communicable


23. Dowling, supra note 4, at 70.

24. See Dowling, supra note 4, at 70. Cervical cancer is the second most common form of cancer in women resulting in 470,000 new cases and 233,000 deaths. Id.

25. HPV Fact Sheet, supra note 1, at 2.

26. See Dowling, supra note 4, at 70-72.

27. Id.
diseases. Modern vaccination practices are credited to the eighteenth century work of Dr. Edward Jenner, whose work gave rise to the field of vaccinology and the development of campaigns aimed at combating the spread of communicable diseases. In 1827, Boston became the first city to require vaccination against smallpox for school enrollment.

The modern era of compulsory vaccination began in the 1970s to control indigenous measles, a communicable disease. State legislatures began using their authority to impose mandatory vaccination for school attendance and certain jobs. Programs such as “no shots, no school,” which instituted mandatory vaccination requirements for school attendance, resulted in high levels of childhood immunization due to strict enforcement. A widely used example illustrating this point took place in Texarkana, Texas, close to the Arkansas border. In 1971, Texarkana did not require measles vaccinations, but its neighboring town in Arkansas bearing the same name

28. See generally OLE LUND ET AL., IMMUNOLOGICAL BIOINFORMATIC (Sorin Istrail et al. eds., 2005). Lund notes that the earliest documented examples of vaccination are from India and China from the seventeenth century. These vaccinations were created using powdered scabs from people infected with smallpox, which use to be a common disease that killed twenty to thirty percent of infected people. Smallpox was responsible for eight to twenty percent of all deaths in several European countries in the 18th century. Id.


30. AM. HERITAGE MED. DICTIONARY (3d ed. 2007) (defining vaccinology as the “science or methodology of vaccine development”).

31. Stern & Market, supra note 29.

32. SWENDIMAN, supra note 10, at 3.

33. Shaw, supra note 12.

34. James J. Hodge & Lawrence O. Gostin, School Vaccination Requirements: Historical, Social, and Legal Perspectives, 90 KY. L.J. 831, 840-45 (2002); see SWENDIMAN, supra note 10, at 4.


36. See Law, supra 35, at 1745-46.
Consequently, when a measles outbreak began, the infection rate in Texarkana, Texas was twelve times higher than the rate in Arkansas.\textsuperscript{38} In light of these results, Texas mandated vaccination for school attendance, which was challenged and upheld by the Supreme Court in 1973.\textsuperscript{39}

Prior to the 1980s, lax enforcement of vaccination requirements by school officials resulted in a low number of immunized children.\textsuperscript{40} However, once school officials were pressured by health officials to enforce these policies, the number of children immunized noticeably increased.\textsuperscript{41} Between 1968 and 1981, the percentage of states using a mandatory vaccination system increased from fifty to 100%.\textsuperscript{42} These policies have been extended further to compel vaccination for day care and college attendance, and as an aspect of approved home-schooling, resulting in an increase in vaccination for those groups as well.\textsuperscript{43} Currently, only Virginia and the District of Columbia require STI vaccination as a precursor for the enrollment of adolescent girls.\textsuperscript{44} Not only is adding a vaccine aimed at preventing against the transfer of a STI very different from the traditional list of communicable diseases, but further extending the mandate to carriers of the disease would be unconstitutional and unprecedented.

IV. THE CONTROVERSIAL HPV VACCINE

A. The History of the HPV Vaccine

Technological advances have helped researchers develop preventive steps to protect the public from contracting communicable, and now non-

\begin{itemize}
\item \textsuperscript{37} \textit{Id.}
\item \textsuperscript{38} \textit{Id. at 1746.}
\item \textsuperscript{39} \textit{Id.}
\item \textsuperscript{40} \textit{Id.}
\item \textsuperscript{41} \textit{Id.} Children and teens are also more likely to be immunized when policies are implemented for early-child education and extend through college admissions. Law, \textit{supra} note 35, at 1746
\item \textsuperscript{42} \textit{Id.}
\item \textsuperscript{43} \textit{Id.}
\item \textsuperscript{44} \textit{Id. at 1762; see HPV Vaccine a Suggestion, Not Mandate, in U.S., supra note 8.}
\end{itemize}
Merck tendered its application for the HPV vaccine, Gardasil®, to the FDA in December 2005. After the vaccine went through the FDA's “fast-track” approval process – lasting only six months – Gardasil was approved for use in females aged nine to twenty-six for the prevention of different forms of cancer. In 2009, the FDA approved Cervarix®, an HPV vaccine manufactured by GlaxoSmithKline, for use in women.

Following the approval of Gardasil®, the Advisory Committee on Immunization Practices (ACIP), a group of fifteen experts chosen by the Secretary of the U.S. Department of Health and Human Services to provide guidance on the control of “vaccine-preventable diseases,” recommended


Gardasil® for routine use by girls aged eleven and twelve in the prevention of HPV, as well as young women aged thirteen to twenty-six on a “catch up” schedule to ensure that all women could have access to the vaccine.\textsuperscript{50} ACIP’s recommendations allowed physicians to distribute the vaccine and recommend it for use in young women, opening the door to the next step: imposing school-based mandates.

\textbf{B. Extending the HPV Vaccine to Men}

After the FDA approved Gardasil® for use in women, Merck continued its research, focusing on extending the vaccine to men.\textsuperscript{51} Doctors and researchers noted, while discussing a possible mandate for women, that requiring girls to be vaccinated, but not requiring men, who make up “half the relevant infectious population,” to be vaccinated would not achieve “herd immunity,” which is essential to stopping the spread of viruses.\textsuperscript{52} “Herd immunity” is achieved when an “entire community is protected against a contagion because a sufficiently large percentage of the group is immune.”\textsuperscript{53} Proponents of extending the vaccine to men would argue that until both sexes are vaccinated, achieving “herd immunity,” the virus would continue to spread.\textsuperscript{54}

On October 16, 2009, after months of lobbying from both sides of the issue, the FDA approved Gardasil® for use in the male population.\textsuperscript{55} The administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications.” \textit{Id.} The overall goals of the ACIP are to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. \textit{Id.}

\textsuperscript{50} See ASHA FAQ, supra note 20; see generally HPV Fact Sheet, supra note 1.

\textsuperscript{51} See What Does Gardasil Mean for Women, supra note 5. On the heels of the FDA approving Gardasil for use in women, the company began researching the possibility of extending it to men and older women. \textit{Id.}

\textsuperscript{52} See Law, supra note 35, at 1761.

\textsuperscript{53} \textit{Id.} at 1762.

\textsuperscript{54} \textit{Id.} at 1763.

\textsuperscript{55} See FDA Approves New Indication for Gardasil, supra note 9; see also FDA Approves Merck’s Gardasil for Boys, supra note 9.
HPV vaccine could prevent some rare forms of cancers in men, such as penile and anal cancer, which normally occur in men engaged in homosexual behavior. Two weeks later, the ACIP approved the vaccine only as a “permissive” rather than “routine” recommendation. Now men can protect themselves from HPV, but this does not open the door for the states to take the unprecedented step of compelling the vaccination of all men based on the sexual behavior of some, or their status as a carrier of the virus to the opposite sex.

V. WHAT ABOUT THE EFFICACY, SAFETY AND COST OF THIS VACCINE?

A. Conflicting Reports on the HPV Vaccine’s Efficacy

There are conflicting reports regarding the HPV vaccine’s efficacy. Since the vaccine is relatively new and went through the “fast-track” approval process, additional testing needs to be conducted to determine its efficacy and safety. Additionally, to impose vaccination on a group of virus carriers, studies should be required to demonstrate that such action is an essential step to preventing the spread of the virus. However, based upon studies finding that ninety percent of women are free from the infection after two years regardless of treatment, vaccination might not be necessary at all. Mandatory vaccination can have positive results, but mandating it to all men would be a drastic step.

56. See generally HPV Fact Sheet, supra note 1; see Office on Women’s Health, Human Papillomavirus (HPV) and Genital Warts FAQ 1, http://www.womenshealth.gov/faq/human-papillomavirus.pdf.

57. See generally Karla Gale, New Vaccine Schedule Says HPV Vaccine Can be Given to Prevent Warts in Men, Reuters (Jan. 4, 2010), http://www.oncolink.org/resources/article.cfm?c=3&s=8&ss=23&Year=2010&Month=01&id=16619. CDC staff reviewed the difference between an affirmative (routine) and permissive recommendation in terms of actions required. An affirmative recommendation requires physicians to offer the vaccine proactively to a VFC-eligible child; a permissive does not. Under both circumstances providers are expected to offer the vaccine if it is requested, but in the case of a permissive recommendation they can refer elsewhere if they don’t stock the vaccine. Immunization programs are expected to promote affirmative recommendations but not permissive recommendation and uptake of a permissive recommendation is not a performance measure for the program. Id.

Addressing the efficacy issue first, the FDA approved a vaccine for use in adolescents after putting it through the “fast-track” approval process. The FDA conducted only four studies of 21,000 women for efficacy over the five-year trial period. Additional questions remain, including the duration of antibody response after vaccination and the impact of vaccination on cancer screening behavior. It is also unclear how long the vaccine will protect against HPV: if it is only temporarily effective, then additional booster shots would be necessary, which would further increase the price. These concerns must be addressed before mandating a vaccine for men that does not fully protect against a non-communicable disease like HPV.

Merck claims that Gardasil® prevents contraction of four HPV strains: types 6, 11, 16 and 18. However, there are over one hundred active strains of HPV that can cause genital warts and other rare cancers. In addition, two recent studies question the effectiveness of the HPV vaccine when the prevalence of HPV in women is closely examined. These studies found that only twenty-six percent of women have an HPV strain, compared to fifty percent as reported by the CDC. Additional data from the National Health

59. See FDA Licenses New Vaccine for Prevention of Cervical Cancer, supra note 47; see also, Law, supra note 35, at 1760.

60. See FDA Licenses New Vaccine for Prevention of Cervical Cancer, supra note 47; see also, Law, supra note 35, at 1738.

61. Kahn, supra note 58, at S14. Kahn notes that additional questions remain concerning provider willingness to recommend the vaccine, the vaccine’s acceptability among parents and adolescents, and the development of effective public health strategies to guarantee immunization in particular areas. Race, geographic region and other factors might affect the efficacy of the HPV vaccine. Id.

62. Id.

63. See FDA Licenses New Vaccine for Prevention of Cervical Cancer, supra note 47.


65. See Lawrence O. Gostin & Catherine D. DeAngelis, Mandatory HPV Vaccine: Public Health vs. Private Wealth, 297 JAMA 17 (2007); see generally Lisa E. Manhart, Human Papillomavirus Infection Among Sexually Active Young Women in the United
and Nutrition Examination Survey concluded that only 26.8% of women were infected. The study found that 3.4% of its participants were infected with at least one of the four “high risk” HPV strands, and that HPV strands 16 and 18 existed in only 1.6%. Reasonable minds could dispute whether twenty-six percent indicates high or low prevalence, but what these studies clearly support is that “the prevalence of strands of HPV protected by the vaccine [is] relatively low.” As a result, Gardasil® only prevents infection in a very small portion of the female population infected with HPV. If Gardasil® only prevents against infection in a small portion of the female population, the sex at risk for cervical cancer, then the tenuous step of compelling vaccination in men, who are mere carriers of the virus, would constitute a greater burden on men than the reciprocal benefit to women.

B. Questions Still Remain Regarding the HPV Vaccine’s Safety

Although general medical community support for the HPV vaccine has been strong, an editorial in the New England Journal of Medicine concluded:

On the one hand, the vaccine has high efficacy against certain HPV types that cause life-threatening disease, and it appears to be safe; delaying vaccination may mean that many women will miss an opportunity for long-lasting protection. On the other hand, a cautious approach may be warranted in light of important unanswered questions about overall vaccine effectiveness, duration of protection, and adverse effects that may emerge over time.

In addition to efficacy, the safety of the HPV vaccine is also unclear, especially when given to men. The FDA only tested the vaccine’s safety in

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66. Dowling, supra note 4, at 72; see also Gostin & DeAngelis, supra note 65.

67. See Dowling, supra note 4, at 72.

68. Id.

69. Id.

11,000 women over the five-year trial period. Although no serious side effects were observed, questions still remain about long-term reactions. As of September 30, 2010, there have been 17,160 reports of adverse effects following Gardasil® vaccination; 1,372 were serious reactions, including fifty-six deaths and other complications, such as Guillain-Barré Syndrome, blood clots and other effects requiring hospitalization or causing permanent disability. It is important to note that most studies and reports regarding the safety of the vaccine apply to women, not men.

C. The Extreme Cost of Vaccination

1. Who Pays the Tab for One of the Most Expensive Vaccine Ever?

Requiring men to get the HPV vaccine is, first and foremost, a burden on the health care system. On the heels of an economic recession and the overhaul of the country’s health care system, the cost effectiveness of a procedure or measure must be part of any health care decision. Gardasil®, the HPV vaccine manufactured by Merck, is one of the most expensive

71. See FDA Licenses New Vaccine for Prevention of Cervical Cancer, supra note 47.

72. See Dowling, supra note 4, at 72.

73. See Reports of Health Concerns Following HPV Vaccination, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccinesafety/Vaccines/HPV/gardasil.html (last visited Oct. 30, 2010). In 1989 Congress passed the national Childhood Vaccine Injury Act which created the Vaccine Adverse Event Reporting System to collect information about adverse reactions to vaccines. Id.

74. See FDA Approves New Indication for Gardasil, supra note 9; Bruce Sylvester, Quadrivalent HPV Vaccine Gardasil Reduces Persistent Anogenital HPV Infection in Men Who Have Sex With Men: Presented at IPV, NAT. AIDS TREATMENT ADVOCACY PROJECT, http://www.natap.org/2009/newsUpdates/ 052009_02.htm (last visited Nov. 17 2010). To date, the only study on HPV vaccine in men was sponsored by Merck and presented at the twenty-fifth International Papillomavirus Congress last month in Sweden. This study concentrated on the efficacy, and not the safety of the vaccine. Id.


vaccines ever produced. Since each dose costs approximately one hundred thirty dollars, it is estimated that the vaccine could cost as much as five hundred dollars when all injections are completed and fees are paid. Other mandatory vaccines required for school enrollment cost far less than Gardasil®, and only require one dose. For instance, private cost for vaccinations for measles, mumps and rubella (MMR) cost fifty dollars per dose; those for chicken pox cost seventy-seven dollars per dose; and those for tetanus cost less than twenty dollars per dose. Although the future of the HPV vaccine in men is still in the preliminary stages of debate, any discussion about compelling such vaccination must be coupled with how the government plans to finance such an expensive and potentially unnecessary vaccine.

Questions continue to circulate concerning the role of private and public insurance in prevention of STIs as opposed to prevention of traditional communicable diseases. Recent trends indicate that the financial burden has been shifting from private to public insurers, which will encumber an already overburdened system. Taxpayers who oppose paying for a vaccine to prevent an STI, or who agree that vaccinating mere carriers is not cost-effective, are likely to place pressure on their respective state legislatures to

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78. ACS FAQ, supra note 22. The American Cancer Society states that “[t]o be most effective, one of the HPV vaccines should be given before a female has any type of sexual contact with another person. Both are given in a series of 3 doses within 6 months.” Id.

79. According to the American Cancer Society, “the drug company price for Gardasil is $130 per dose, and Cervarix is $128 per dose.” ACS FAQ, supra note 22; Hodge & Gostin, supra note 34, at 845. The Center for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) recommends vaccination for girls aged eleven to twelve, although the series can be started as early as nine years old. ACIP also recommends a “catch up” series for women aged thirteen to twenty-six years old. See Thomas C. Wright, The New HPV Vaccine: What the ObGyn Needs to Know, 19 J. FAM. PRAC. 1 (2007).

80. CDC Vaccine Price List, supra note 77.

81. ASHA FAQ, supra note 20.

82. Id.
deny public funding.\textsuperscript{83} Because state legislatures are the primary leaders in regulating health insurance, immunization laws vary by state and therefore affect private insurance companies who rely on ACIP recommendations when deciding what vaccines to cover.\textsuperscript{84}

2. Compelling Men to be Vaccinated is not Cost Effective

In addition to the cost of the vaccine, the policy goals behind immunizing men are questionable. Although studies continue to find that vaccinating women is "within the threshold for good value," adding men to the equation "[does] not outweigh the costs."\textsuperscript{85} A recent study by Harvard researchers published in the \textit{British Medical Journal} concluded that vaccinating men against HPV does not appear to be cost effective.\textsuperscript{86} The study analyzed the cost effectiveness of adding men to current vaccination programs.\textsuperscript{87} Researchers used mathematical models based on data from clinical trials, population studies, and cost data to measure the incremental cost effectiveness ratios, which are expressed as cost quality adjusted life year (QALY), a mathematical formula that measures the burden of disease on the quality and the quantity of life lived.\textsuperscript{88} Vaccinating twelve-year-old girls – assuming seventy-five percent get the shots and the vaccine lasts a lifetime –

\begin{itemize}
  \item \textsuperscript{83} \textit{Id.}
  \item \textsuperscript{84} \textit{Id.} Most private insurance companies include most, if not all, of ACIP recommended vaccines in their benefit programs. \textit{Id.}
  \item \textsuperscript{86} Jane J. Kim & Sue J. Goldie, \textit{Cost effectiveness analysis of including boys in a human papillomavirus vaccination programme in the United States}, 339 B.M.J. 3884 (2009), http://www.bmj.com/content/339/bmj.b3884.full.pdf. \textit{See also} Steenhuysen, \textit{supra} note 85.
  \item \textsuperscript{87} Kim, \textit{supra} note 86 at 1. Current programs include routine screening beginning in women around the age of 20 or three years after their first sexual intercourse. \textit{Vaccinating Boys Against Human Papillomavirus (HPV) Not Cost Effective}, \textit{MED. NEWS TODAY} (Oct. 9, 2009), http://www.medicalnewstoday.com/articles/166903.php.
  \item \textsuperscript{88} Kim, \textit{supra} note 86, at 1; \textit{see Measuring Effectiveness and Cost Effectiveness: the QALY}, \textit{NAT. INST. FOR HEALTH AND CLINICAL EXCELLENCE} (Apr. 20, 2010), http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenessstheqaly.jsp; \textit{see also} \textit{Vaccinating Boys Against Human Papillomavirus (HPV) Not Cost Effective}, \textit{MED. NEWS TODAY} (Oct. 9, 2009), http://www.medicalnewstoday.com/articles/166903.php.
\end{itemize}
will lead to a cost-effectiveness ratio of less than $50,000 per QALY.\textsuperscript{89} Under the same assumptions, adding men to the equation caused the ratio to exceed $100,000.\textsuperscript{90}

While some argue that the spread of HPV has turned into an epidemic,\textsuperscript{91} the 3,700 deaths per year from cervical cancer\textsuperscript{92} do not compare to the thirty to fifty million deaths recorded during the 1918 influenza pandemic.\textsuperscript{93} Further, even though HPV is the main "etiological cause step" in cervical cancer, there are other risk factors including giving birth, smoking, using oral contraceptives, having numerous sexual partners, and having a weak immune system.\textsuperscript{94} The HPV vaccine does not affect any of these other factors. Therefore, when taking all risk factors into account, compelling men to be vaccinated against HPV would only slightly affect the number of women infected with HPV or suffering from cervical cancer. It would however, severely burden men by forcing them to take the unnecessary and expensive trip to their doctor.

Researchers acknowledge that since the vaccine is new and additional tests need to be conducted to learn more about it, additional health benefits may not be known.\textsuperscript{95} Regardless, Jane Kim of the Harvard School of Public Health, whose study appears in the \textit{British Medical Journal}, says her results imply that "there may be better uses and other health interventions that

\textsuperscript{89} Kim, supra note 86 at 3; see Measuring Effectiveness, supra note 88; see also Vaccinating Boys, supra note 88.

\textsuperscript{90} Kim, supra note 86 at 3; see also Measuring Effectiveness, supra note 88; Vaccinating Boys, supra note 88.


\textsuperscript{92} Dowling, supra note 4, at 70.

\textsuperscript{93} See Survivors Remember 1918 Global Flu Pandemic, MSNBC.COM (Dec. 17, 2006), http://www.msnbc.msn.com/id/16194254/. The 1918 flu pandemic killed "at least 50 million people and perhaps as many as 100 million" people. \textit{Id.}

\textsuperscript{94} See Dowling, supra note 4, at 70-71; see also J. Brisson et al., Risk Factors for Cervical Intraepithelial Neoplasia: Differences Between Low- and High-Grade Lesions, 140 AM. J. EPIDEMIOL 700, 701, 704, 707 (1994).

\textsuperscript{95} Steenhuyssen, supra note 85; see Measuring Effectiveness, supra note 88; see also Vaccinating Boys, supra note 88.
would increase health gains in the population." It is not fiscally responsible for the government, given the United States' current budget situation and the rising costs of health care, to expend limited resources to programs and initiatives that are not cost-effective.

VI. COMPELLING HPV VACCINATION IMPINGES ON PRIVACY RIGHTS

A. The Basic Right to Privacy

In addition to its constitutionality being questionable at best, mandatory vaccination of mere carriers of a virus would impinge on the basic right to privacy, a right which has been an integral part of our country's history. The right to privacy is simple: it is the "right to be let [sic] alone." Before Louis Brandeis was a Supreme Court Justice, he wrote one of the most influential articles discussing privacy rights, The Right to Privacy, in which he discusses the basic right and its limitations. Brandeis opens by stating "the individual shall have full protection in person and in property . . . but it has been found necessary from time to time to define anew the exact nature and extent of such protection." Writing this article in response to invasions by government and the media, Brandeis contends the "traditional" right to privacy, including protection of tangible items through the writs of battery, libel and trespass, must be expanded to create a new right encompassing intangible protection against assault and slander. In support of this view, he argues that it is the court's "purpose to consider whether the existing law affords a principle which can properly be invoked to protect the privacy of the individual; and, if it does, what the nature and extent of such protection is." The nature and extent of such protection is precisely the point of contention in current debate over HPV vaccination.

There are two sides to this debate. Proponents of vaccination would argue for the HPV vaccine as an appropriate invasion into a man's privacy.

96. Steenhuysen, supra note 85; see also Kim, supra note 86; Vaccinating Boys, supra note 88.


98. See id. at 193, 195, 197.

99. Id. at 193.

100. See id. at 193-95.

101. Id. at 197.
Opponents of compelled vaccination for men would argue that even viewing the vaccination as a “public necessity,” compelling a carrier of an infection to be vaccinated is an invasion of personal privacy. As Brandeis would contend, “[w]e must therefore conclude that the rights, so protected, whatever their exact nature . . . are rights as against the world.” The evolution of the basic right to privacy must be protected against action to compel virus carriers to be vaccinated, the newest form of government intrusion.

B. American Courts Must Follow Precedent Protecting Privacy Rights

Early American case law addressed the competing interests of protecting the public against disease and defending public rights against invasion of the government by allowing school boards and state legislatures to enforce such mandatory vaccination programs. These early cases were issued during a time when smallpox was a major epidemic contributing to a fatality rate of approximately thirty-five percent of the population, and controlling its spread protected the public at large. The development of the HPV vaccine has been said to be of “major public health importance” because of the potential impact it could have on women’s health. However true or untrue that may be, compelling vaccination requires a balancing of private choice and state interests.

The Tenth Amendment to the Constitution states that all powers not delegated to the Federal government are reserved to the state. These traditional police powers are reserved to states allowing for state control on issues “relate[d] to the safety, health, morals, and general welfare of the public.” The Supreme Court held that when a state exercises these powers, public health should be balanced against “medical considerations,

102. Id. at 213.


104. See Shaw, supra note 12, at 107.


106. U.S. CONST. amend. X.

personal autonomy, parental rights, and the religious and personal philosophy of the individual."\textsuperscript{108}

The HPV vaccine debate highlights the tension between "civil liberties and public health" concerns.\textsuperscript{109} Traditionally, the Supreme Court has been hesitant to impinge on one's right of privacy.\textsuperscript{110} For example, in \textit{Griswold v. Connecticut}, the Supreme Court invalidated a state statute preventing the use of contraceptives, on the premise that one has a right to privacy.\textsuperscript{111} The underpinnings of privacy in \textit{Griswold} have set the stage for the modern doctrine of privacy.\textsuperscript{112} In his opinion, Justice William O. Douglas argues that protection from government intrusion into marital privacy was a constitutional right, one that is a "penumbra" growing out of our constitutional protections.\textsuperscript{113} Later decisions have noted the \textit{Griswold} Court's instruction: "governmental purpose to control or prevent activities constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedom."\textsuperscript{114} Although a federal mandate has not been introduced, the only way a potential mandate could be implement would be a federal mandate by invading the area of law normally governed by the state.

Proponents of mandatory vaccination in men and women argue that cervical cancer poses a public health risk and society as a whole should do everything possible to prevent the virus from spreading.\textsuperscript{115} Although it is

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  \item \textsuperscript{109} Dowling, \textit{supra} note 4, at 67, n. 18 (citing Lawrence O. Gostin, \textit{PUB. HEALTH LAW: POWER DUTY, RESTRAINT} 21 (2000)).
  \item \textsuperscript{111} \textit{See Griswold}, 381 U.S. at 480, 485.
  \item \textsuperscript{112} \textit{See id}.
  \item \textsuperscript{113} \textit{Id} at 483, 484-86.
  \item \textsuperscript{115} Shaw, \textit{supra} note 12, at 108.
\end{itemize}
true that many women suffer from cervical cancer, it is hardly a public health risk when compared to the millions affected by epidemics in the last century.\footnote{See Survivors Remember 1918 Global Flu Pandemic, supra note 93. The 1918 flu pandemic killed "at least 50 million people and perhaps as many as 100 million" people. Id.} Furthermore, as discussed earlier, there are other factors that impact a woman’s chance of suffering from cervical cancer, and there are screening precautions, such as a pap smear, that women can use to protect themselves.\footnote{See Dowling, supra note 4, at 70-71; see also Brisson, supra note 94.} Even when taking into account all of these factors, they do not outweigh the opposing argument that compelling immunization on carriers is not only an infringement on one’s privacy, but also runs counter to public policy and what the American courts have permitted throughout their history.

\section*{C. The Roe Effect}

Privacy rights were again strengthened by the landmark decision \textit{Roe v. Wade}, where the Supreme Court set forth the precedent for other cases to disallow state and federal restrictions on abortion by citing the Constitution’s right to privacy emanating from the Due Process Clause of the Fourteenth Amendment.\footnote{Roe v. Wade, 410 U.S. 113, 152-55 (1973). In \textit{Roe}, the United States Supreme Court concluded that the “right of privacy, whether it be founded in the Fourteenth Amendment’s concept of personal liberty and restrictions upon state action . . . or . . . in the Ninth Amendment’s reservation of rights to the people, is broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.” Id. at 153.} Justice Blackmun writing for the Court asserted that the “right of privacy . . . found\footnote{Id. at 153.} in the Fourteenth Amendment’s concept of personal liberty and restrictions upon state action . . . is broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.”\footnote{Id.} This precedent firmly establishes that a government should not compel a woman, or a man, to take action in regards to their body that does not protect the public.

Citing \textit{Roe}, courts have further recognized that “regulation[s] limiting . . . [fundamental] rights may be justified only by a ‘compelling state interest’ . . . and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake.”\footnote{Women’s Cmty. Health Ctr., Inc. v. Cohen, 477 F. Supp. 542, 545 (D. Me. 1979) (citing \textit{Roe}, 410 U.S. at 155).} The \textit{Roe} Court balanced the interest in
the mother’s health against the interest of protecting life, concluding that during the first trimester, “the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman’s attending physician” and “free of interference by the State.” Cases following Roe make clear that “if the challenged state action does not impinge upon a woman’s decision to have an abortion and does not place obstacles in the path of effectuating that decision, the regulation need only be justified by a rational relationship to a legitimate state purpose.” With regard to the debate on the HPV vaccine, compelling vaccination would only be justified under the rationale set forth in Roe when there is a compelling state interest. This is not present in the current debate.

Similarly, opponents of vaccinating men would argue that government intrusion would restrict personal judgment pertaining to medical decisions. Recognizing that the vaccine is currently approved, the decision to be vaccinated should be left to the personal judgment of each man coupled with solicited medical judgment from the man’s physician. Any government interference should only occur when a legitimate state interest is involved, which is not the case, as discussed in Part II.

VII. THE CONSTITUTIONAL STANDARD OF COMPELLING VACCINATION

A. Jacobson v. Massachusetts

Although the HPV vaccine is currently approved for permissive use, this Note argues that the logical progression would involve a push for mandatory vaccination. As discussed in Part III, the American medical community has relied heavily on school-based mandates to compel vaccination. Even with historic precedent and numerous local cases approving legislation to compel vaccination, courts have allowed for exceptions based on religious,

121. Roe, 410 U.S. at 162-64.
123. See Part II, supra.
124. See Law, supra note 35, at 1762-64. Herd immunity is achieved when an “entire community is protected against a contagion because a sufficiently large percentage of the group is immune.” Id. at 1762. See also Shaw, supra note 12, at 108. Accepting the premise that herd immunity is the next step after vaccine approval, Shaw notes that proponents argue steps such as, “[v]accination are necessary in a public health sense, to control disease.” Id.
125. See Part III, supra.
scientific, and philosophical beliefs. Historically, legislation mandating vaccinations "for diseases transmitted through the air because such diseases are much more difficult to combat; no specific behavior--other than simply being in the same room as another infected person--makes a person more susceptible to infection". Although these early decisions paved the way for state legislatures to pass laws compelling vaccination for communicable diseases, the judiciary did limit mandatory vaccination in some cases where religious beliefs provided good reason for noncompliance.

The Supreme Court's majority opinion in Jacobson v. Massachusetts laid out the constitutional requirements for such decisions. Jacobson was a Massachusetts citizen, who, for philosophical reasons, opposed the compulsory smallpox vaccine because he did not believe it worked. He also objected to the compulsory vaccination law calling it "unreasonable, arbitrary and oppressive, and therefore, hostile to the inherent right of every freeman to care for his own body and health . . .". After refusing the vaccine, he was charged and fined. Jacobson argued that he had a

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126. Jonathan T. Scott, The Difficult Road to Compelling Vaccination for Sexually Transmitted Diseases -- How Gardasil and Those to Follow Will Change the Way that States Require Inoculation, 97 Ky. L.J. 697, 707 (2009). Most courts addressed this issue by allowing for exceptions to mandatory vaccination laws. Those that object to vaccination have been making arguments since the nineteenth century objecting on moral, intellectual and philosophical levels. Religious objectors carved out another group of "anti-vaccinationists," who tend to receive far more protection under Jacobson and in modern cases. Id. at 705-06.

127. Dowling, supra note 4, at 80. These diseases do not require additional behavior. Merely being in the same room or walking by a person can result in a transfer of the disease. Id.

128. Scott, supra note 126, at 701-02, 707-08. Most courts addressed this issue by allowing for exceptions to mandatory vaccination laws. Id. at 706.

129. See Jacobson v. Massachusetts, 197 U.S. 11, 11 (1905) (holding that is a valid exercise of police power to delegate to local boards of health authority to require, under penalty, the vaccination of all citizens where it may be deemed necessary to the public health and safety; and such necessity arises when smallpox is present in a community, or its appearance may be reasonably apprehended). See also Dowling, supra note 4, at 68; see also Scott, supra note 126, at 700.


131. Id. at 26.

132. Id. at 12-14.
constitutional right under the Fourteenth Amendment to refuse compulsory vaccinations. The Court disagreed stating that in pursuing the common good, "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."

The Jacobson Court recognized there are limits to states' police powers by laying out five criteria that legislatures must meet before requiring compulsory vaccinations. The initial factor requires a "public health necessity" to "prompt the restriction." The Court notes that states cannot exercise powers in "an arbitrary, unreasonable manner" or "go so far beyond what [is] reasonably required for the safety of the public." Next, the Court calls for a "reasonable relationship between the public health intervention and the achievement of a legitimate public health objective." Next, there must be a "real or substantial relation" between the safeguards implemented and the public health concern, and that such safeguards are not just a 'plain, palpable invasion of rights." The fourth factor considers whether the action or regulation is "proportional to the risk," finding interventions that are "gratuitously onerous or unfair" unconstitutional. The final factor requires that the measure or vaccination cannot pose a health risk to the individual. Summing up this seminal decision, Jacobson advances two notions: "that police powers authorize states to compel vaccination for the public good, and that government power is only constitutionally acceptable if exercised reasonably."

133. Id. at 13-14.

134. Jacobson, 197 U.S. at 28; see also Dowling, supra note 4, at 68.

135. See Dowling, supra note 4, at 68.

136. Id.; see also Jacobson, 197 U.S. at 28-29.

137. Jacobson, 197 U.S. at 28; see Dowling, supra note 4, at 68.

138. Dowling, supra note 4, at 68; see Jacobson, 197 U.S. at 26-27.


140. Dowling, supra note 4, at 68; Hodge & Gostin, supra note 34, at 856.

141. See Dowling, supra note 4, at 68; see also Jacobson, 197 U.S. at 39.

142. Dowling, supra note 4, at 68.
B. The HPV Vaccine Does Not Pass Muster Under Jacobson

The American legal system aims to balance the rights of its citizens against the goals of society without upsetting either.\textsuperscript{143} While preventing disease is important to society, legislatures that compel vaccinations must thoroughly evaluate all the risks, benefits, and consequences before making such a decision. Legislatures should use the factors outlined by the Supreme Court in \textit{Jacobson} as their guide. As noted above, \textit{Jacobson} sets out the factors/requirements that mandatory action must meet in order to be constitutional. As discussed in Part IV of this Note, compelling the use of the HPV vaccine would fail the final \textit{Jacobson} factor regarding the safety and efficacy of the vaccine. In addition, legislation compelling the use of the HPV vaccine also fails to meet the four remaining \textit{Jacobson} factors, as discussed below. Proponents of mandatory vaccination argue that cervical cancer is a public health concern that could be prevented by vaccinating young girls and men before they become sexually active, creating herd immunity.\textsuperscript{144} Studies have shown that to achieve herd immunity, between seventy-five and ninety percent of the population must be vaccinated.\textsuperscript{145} The only way to achieve such a large percentage is to mandate vaccinations of both men and women. Opponents of mandatory vaccinations argue that the vaccine does not address a health necessity, is not safe or effective, and would be unconstitutional if compelled.

1. Cervical Cancer Does Not Implicate a Health Necessity

A \textit{Jacobson} analysis is triggered by a “public health necessity.”\textsuperscript{146} Although HPV can lead to cancer in some individuals, for most, it disappears without the person ever being aware of the infection.\textsuperscript{147} Studies indicate that 3,700 to 3,900 women die each year from cervical cancer.\textsuperscript{148}

\begin{footnotesize}

\textsuperscript{144} See Law, supra note 35 at 1761-62; see also Shaw, supra note 12, at 108.

\textsuperscript{145} See Law, supra note 35 at 1761-62; see also Shaw, supra note 12, at 108.

\textsuperscript{146} Dowling, supra note 4, at 68.

\textsuperscript{147} See generally HPV Fact Sheet, supra note 1.

\textsuperscript{148} See Dowling, supra note 4, at 80 (estimating 3,700 annual deaths from cervical cancer); see also Allen Craig, Abigail English, Frederci E. Shaw & Lance Rodewald, \textit{New Adolescent Vaccines: Legal and Legislative Issues}, 35 J.L. Med. & Ethics 106, 106 (2007) (noting 3,900 deaths from cervical cancer annually); see generally HPV Fact Sheet, supra note 1.
\end{footnotesize}
representing only "0.001%] of the population in the United States or .002[\%] of the female population." Though it is a horrible disease, HPV is clearly not a public health epidemic. In contrast, both measles and smallpox were communicable diseases that had major impacts on the safety of the public, and therefore, justified compulsory vaccinations.

2. No "Reasonable Relationship" Exists Between Compelling Vaccination and Achieving the Goal of Decreasing Cervical Cancer

Next, the Jacobson court examined the relationship between the "public health intervention and achievement of a legitimate public health objective." Even assuming a court would find that cervical cancer is a

149. See Dowling, supra note 4, at 80 (estimating 3,700 annual deaths from cervical cancer); see also Craig, supra note 148, at 106; see generally HPV Fact Sheet, supra note 1.

150. See How Poxviruses Such as Smallpox Evade the Immune System, SCIENCE DAILY.COM, http://www.sciencedaily.com/releases/2008/01/080131122956.htm (last visited Nov. 7, 2010) (asserting that "[t]he [smallpox] virus is estimated to have caused between 300 million and 500 million deaths in the 20th century alone."); see also WORLD HEALTH ORG., FACT SHEET ON MEASLES 1 (2009), http://www.who.int/mediacentre/factsheets/fs286/en/ (explaining that measles is a "highly contagious, serious disease" and caused "nearly 450 deaths every day" in 2008); see also Shaw, supra note 12, at 107 (identifying a smallpox death rate of thirty-five percent). Mandates for vaccinations against dangerous, highly communicable diseases are much easier to justify. Oral polio is an example from the past. Oral polio vaccine was, up to about the year 2000, required in all 50 states (an injectable form of polio vaccine succeeded it). The oral vaccine contained (and continues to contain, as it is used in other countries) live virus and carries with it a tiny risk (perhaps about 1 in 2.4 million in the United States) of developing paralysis from the vaccine virus itself. On the other hand, in 2000, an American child being vaccinated with oral polio vaccine faced virtually no risk of infection with wild polio virus, since it had been virtually eliminated from the Western hemisphere and was increasingly rare in the rest of the world. Thus, in 2000, parents could have made a rational decision for their child to avoid any risk of vaccine-induced paralysis by refusing vaccination and allowing their child to free-ride on the vaccine-induced immunity of others. If enough parents took that same course, the population would experience a gradual increase in susceptibility to polio virus. Over time, assuming the virus continued to circulate in the world, an outbreak of polio might occur in the U.S. population. It is in this situation, mandatory vaccination against dangerous highly communicable diseases, when the interests of parents as individuals conflict with the interests of the whole, that the justification for vaccination mandates are at their strongest. Id. at 108.

151. Dowling, supra note 4, at 68.
public health necessity, it would not find a reasonable relationship between vaccinating carriers of a virus and those who develop cervical cancer. Vaccinating men, who are mere carriers, makes the discussion more attenuated in light of the second factor's need to show a reasonable relationship between the intervention and public health objectives. Curtailing the spread of HPV is an important objective, but is one that encompasses many more facets than just mandating a vaccine to a large portion of the population.

Unlike diseases such as smallpox or the chickenpox, HPV is not an airborne, highly infectious disease, posing no immediate risk to children at schools.\textsuperscript{152} Mandatory vaccinations that would protect the interests of the public as a whole prevailed over individual freedoms when smallpox vaccinations were debated.\textsuperscript{153} Most vaccines that are mandatory for school enrollment "protect against highly contagious diseases that cause significant morbidity and mortality and threaten both the individual and the community."\textsuperscript{154} Acknowledging that the HPV vaccine does prevent the prevalence of HPV infections, it is still unclear whether HPV is a true threat to the general welfare.\textsuperscript{155}

A similar policy involving the vaccination of one segment of the population for the primary purpose of reducing the incidence of a disease in another segment was debated in regards to the rubella vaccine.\textsuperscript{156} The vaccine is given to all children to reduce the incidence of "congenital defects in infants born to women who contract rubella during pregnancy."\textsuperscript{157} However, "sexually transmitted diseases can generally be avoided through a

\begin{itemize}
\item \textsuperscript{152} See Hodge & Gostin, supra note 34, at 845; see also Dowling, supra, note 4, at 81 (noting that "HPV can be contained through behavioral changes and is not communicable through ordinary daily interactions.").
\item \textsuperscript{153} See Shaw, supra note 12, at 107.
\item \textsuperscript{154} Dowling, supra, note 4, at 81.
\item \textsuperscript{155} Id.
\item \textsuperscript{157} Id.
\end{itemize}
specific behavior change which an individual usually has full control over.”158

A more recent debate concerning the Hepatitis B vaccine is more comparable to the HPV vaccine because it also seeks to prevent the spread of a sexually-transmitted disease.159 However, Hepatitis B is not merely a sexually transmitted disease; it can also be contracted through blood and bodily fluid transmission.160 One can refrain from contracting HPV by changing sexual behavior, an option that is not always successful in preventing Hepatitis B transmission. Those who “accept[] the view that such laws are justified only by the state’s prerogative to protect the whole, and are not justified by the state’s desire to protect individuals from the consequences of their own behavior” have a hard time accepting laws mandating vaccines for viruses transferred through behavior.161

3. The Action is Not Proportional to the Prevalence of Cervical Cancer

The Jacobson Court finally examined whether government action was “proportional to the risk” of the disease.162 A court cannot find that the proposed action of vaccinating every adolescent against a virus is proportional if HPV only causes cancer in 0.002% of the population.163 Mandating carriers of a virus to pay for such an expensive vaccine is not proportional, especially in light of other preventative measures such as pap smears, which have been effective in detecting abnormal cells and cervical cancer for over fifty years.164 A stronger argument for proportionality may

158. See Dowling, supra note 4, at 80. The recent debate concerning the Hepatitis B vaccine is more comparable to the HPV vaccine because it also seeks to prevent the spread of a sexually-transmitted disease. Id.

159. See Dowling, supra note 4, at 80.

160. See Dowling, supra note 4, at 80, n.156 (citing Richard K Zimmerman, Ethical Analysis of HPV Vaccine Policy Options, 24 VACCINE 4812, 4815 (2006)).

161. See Shaw, supra note 12, at 108.

162. Dowling, supra note 4, at 68.

163. See Dowling, supra note 4, at 68, 80 (estimating 3,700 annual deaths from cervical cancer); see also Craig, supra note 148, at 106; see generally HPV Fact Sheet, supra note 1.

164. Law, supra note 35, at 1735-36. Since the 1950s doctors have used this procedure to identify potential abnormalities in the cervix, which could lead to an
be to mandate the HPV vaccine for girls since they risk being directly affected by cervical cancer; however, this argument is not without gaps. The American College of Obstetricians and Gynecologists (ACOG) guidelines recently increased the age recommendation for having annual pap smears, but the exam "continue[s] to be essential to detect cervical cancers." In addition, a new DNA test was revealed that could be more effective than a pap smear. The ACOG notes that "only 0.1 percent of cervical cancer occurs in women under 21 years of age in part . . . because young women’s immune systems are strong enough to fight off HPV before it causes cancer." The HPV vaccine is not a shortcut to prevention, only an added level of protection because there is still a chance of an irregular pap smear even after vaccination. Further "most pap test abnormalities are caused by HPV types not preventable with current vaccines." Thus, if up to ninety percent of HPV infections are "cleared on their own in adolescents within a few years" and women are still urged to go to the gynecologists

infection or cervical cancer. Today, doctors annually perform more than fifty million pap smear procedures and only five percent are abnormal requiring additional tests. Id. at 1736. These traditional procedures have benefited women and are proportional.


167. See Cox & Hundert, supra note 165.


169. See generally Brotherton & Heley. supra note 168.

170. See generally Cox & Hundert, supra note 165.
for annual pap smears after their twenty-first birthday, then mandating vaccination of a carrier group seems overly burdensome and unnecessarily expensive when the target group continues to adhere to traditional practices.

VIII. WHERE STATES STAND? STATE LEGISLATURES DIFFER OVER VACCINATION

There is no current legislation pending that would mandate the HPV vaccination for men, but that is most likely due to the fact that the vaccine was only recently approved for use in men. Once a vaccine is approved by the CDC and recommended by the ACIP, states begin to debate over requirements and mandates. Some state legislatures have granted their state’s health departments the power to create mandates and requirements. Debate at the state level has focused on compelling girls to be vaccinated for school admission, with even HPV vaccine supporters citing concerns about safety, cost and parental rights. States that make the vaccine mandatory “must also address funding issues, including for Medicaid and SCHIP coverage and youth who are uninsured, and whether to require coverage by insurance plans.”

Shortly after the CDC’s approval of the HPV vaccine in women, Michigan became the first state senate to introduce legislation requiring the HPV vaccine for sixth grade girls, but the bill was not enacted. As of September 2009, forty-one states and the District of Columbia have introduced legislation to “require, fund or educate the public” about the HPV vaccine. At least nineteen states have enacted such legislation. Other states, such as New Hampshire and South Dakota, have taken another approach, providing the vaccine at no cost to girls under the age of


172. Id.

173. Id. “The HPV vaccine is available through the federal Vaccine for Children (VFC) program in all 50 states . . . and Washington, DC.” Id. VFC provides vaccines for children covered by Medicaid and some underinsured or uninsured children under the age of eighteen. Id.

174. Id.

175. Id.

176. HPV Vaccine: State Legislation and Statutes, supra note 171.
Currently, only Virginia and Washington, D.C., have approved school attendance mandates for sixth-grade girls allowing parents an "opt-out" for any reason. Although these school-based mandates provide parents with an opt-out, this trend moves the debate in a direction that would open the door to compelling vaccination for men. Eventually state governments may begin mandating sixth-grade boys to receive the HPV vaccine to be eligible for school attendance. Such state intervention would grossly exceed the traditional justifications for compelling vaccinations. As the debate continues, legislators must think through this issue carefully and consider actual public harm.

IX. CONCLUSION

After all the arguments are debated and the factors considered, there is no reason to rationally support extending mandatory HPV vaccination to men. Opponents are not arguing the vaccine should not be available, but rather that it should not be mandatory for school enrollment. The government should not be in the business of mandating vaccination to carriers of a virus when the threat to the public is not imminent or serious. Not only would such action be unconstitutional, but questions also remain regarding the safety and efficacy of the vaccine. In addition, the cost of implementing such a requirement would be overly burdensome to an already stretched healthcare system. Recognizing that mandatory vaccination for communicable viruses does benefit the public, the government should not intervene when a virus can be curbed by changing behavior and can be detected and treated by more cost-effective means, such as pap smears. Therefore, compelled HPV vaccination should not be implemented by the government and efforts to stop such action should be supported by all Americans.

177. Id.

178. See HPV Vaccine a Suggestion, supra note 8.