

**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**

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I. INTRODUCTION

Most individuals want to live long, healthy lives. Consequently, society values the protection of its members from illness. In order to protect its members from disease, society often requires that children be vaccinated against certain illnesses as a prerequisite to school entry. By mandating that students be vaccinated, society infringes on another important value: a parent's right to make decisions regarding his or her own children. Society must choose which values its laws will protect—a complex decision. Currently, states are confronted with deciding whether school-age girls should be required to receive vaccination against human papillomavirus (HPV),¹ a sexually transmitted disease that can result in genital warts and cervical cancer.² Because HPV is not an airborne disease and a dearth of information regarding long term effects of HPV vaccination, mandating the vaccine is a violation of parental rights.

The debate about vaccination resurfaced in the news after the Food and Drug Administration (FDA) approved Gardasil, a vaccine manufactured by Merck Pharmaceuticals that protects against four³

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¹ Stephanie Saul & Andrew Pollack, *Furor on Rush to Require Cervical Cancer Vaccine*, N.Y. TIMES, Feb. 17, 2007, at A2.

² CENTERS FOR DISEASE CONTROL AND PREVENTION, GENITAL HPV INFECTION: CDC FACT SHEET (2004), <http://www.cdc.gov/std/HPV/hpv.pdf>.

³ Press Release, U.S. Food and Drug Admin. [FDA], FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), *available at* <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.

of the over one hundred⁴ strands of HPV. Many state legislators have introduced bills to add HPV vaccination to the states' vaccination schedules for girls' middle school attendance. Virginia⁵ and Washington D.C.⁶ are the only jurisdictions already to have passed a requirement for HPV vaccination. At least thirteen other state legislatures are currently considering enactment of such legislation.⁷

⁴ CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 2.

⁵ VA. CODE ANN. § 32.1-46(D)(3) (2007).

⁶ D.C. CODE ANN. § 7-1651.04 (Lexis Nexis 2007).

⁷ California Assembly Bill 16 requires any female pupil admitted to any school at the sixth grade level to receive the HPV vaccine but provides for no "special" exemption. Assem. B. 16, 2007-2008 Assem., Reg. Sess. (Cal. 2006). Connecticut House Bill 6977 requires, "[b]efore being permitted to enter sixth grade a child shall receive an initial dose of human papilloma virus vaccine consistent with the most recent recommendations of the National Immunization Practices Advisory Committee." H.B. 6977, 2007 Gen. Assem., Jan. Sess. (Conn. 2007). The Connecticut bill interestingly does not specify that it applies to girls only. *Id.* Georgia Senate Bill 155 requires vaccination for all female students prior to entering sixth grade. S.B. 155, 149th Gen. Assem., Reg. Sess. (Ga. 2007). This provision is to sunset on July 1, 2011. *Id.* Illinois Senate Bill 10 requires female students ten or eleven years old to provide proof of vaccination or a letter from a parent stating he or she does not want the girl vaccinated. S.B. 10, 95th Gen. Assem., Reg. Sess. (Ill. 2007), *available at* <http://www.ilga.gov/legislation/95/SB/09500SB0010.htm>. Kansas House Bill 2227 requires proof of vaccination but allows parents or guardians to opt-out by sending a letter indicating he or she has received information about the vaccine and that vaccination would be against his or her religious beliefs. H.B. 2227, 82nd Leg., Reg. Sess. (Kan. 2007). Kentucky House Bill 345, which passed the House and is awaiting passage in the Senate, requires HPV vaccination, but a parent or guardian may exempt his or her daughter for any reason. H.B. 345, 2007 Sess. (Ky. 2007). Michigan House Bill 4164 was referred to committee and requires immunization for children entering sixth grade. H.B. 4164, 94th Leg., Reg. Sess. (Mich. 2007). Additionally, Michigan House Bill 4104 states that a parent of a female child enrolling in sixth grade must provide either a statement from her physician stating that the girl has received HPV vaccination or a statement from a parent or guardian that he or she has received information about the vaccine and opted to decline its administration. H.B. 4104, 94th Leg., Reg. Sess. (Mich. 2007). Minnesota Senate Bill 243 requires HPV vaccination for females age twelve and over, but they can opt-out with a signed statement from a parent or guardian. S.B. 243, 85th Leg., 1st Reg. Sess. (Minn. 2007). Missouri House Bill 2230 adds HPV vaccination to the state's vaccination schedule for girls to enter grade six, but at the option of her parent or guardian.. H.B. 2230, 94th Gen. Assem., 2d Reg. Sess. (Mo. 2008). A separate Missouri bill specified that no student should be denied entry from school for failure to be vaccinated against HPV. S.B. 104, 95th Leg., 1st Reg. Sess. (Mo. 2009). New York Assembly Bill 778 would require administration of the HPV vaccine to enter school. Assem. B. 778, 2009-2010 Leg., 231st Sess. (N.Y. 2009); Ohio House Bill 81 requires all female students to receive the vaccine, but parents can opt out upon receiving information. H.B. 81, 127th Gen. Assem., 2007-2008 Sess. (Ohio 2007). Vermont House Bill 256 requires that girls entering grade six show evidence of vaccination or parents can object on religious and moral grounds but must also sign a statement acknowledging the receipt of information regarding HPV. H.B. 256, 2007-2008 Leg. Sess. (Vt. 2007), *available at* <http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2008/bills/intro/H-256.HTM>. West Virginia House Bill 2835 requires vaccination for girls

State governments have been using century-old legal precedent developed under dramatically different conditions to permit mandatory vaccination of school age children, including HPV vaccination.⁸ While there is no right to education,⁹ requiring vaccination for school entry is in practical terms a mandate. This Comment argues that states should not require vaccination against HPV because such a requirement would violate parental rights and the legal precedent that states use to approve new vaccinations is based on circumstances that have changed significantly over the past hundred years, and, therefore, should no longer apply. State governments should not require any vaccination, including HPV vaccination, as a prerequisite to school entry unless there is a public health need that would make it permissible for the government to require the vaccination for all its citizens, adult and child.

In Part II, this Comment examines the new HPV vaccine and the potential public health consequences that may result from its introduction. In Part III, the Comment then addresses the legal framework surrounding mandatory vaccination in the United States and how the public health concerns underlying this framework do not justify mandatory HPV vaccination. In Part IV, this Comment posits that parental rights dictate that HPV vaccination should not be required as a prerequisite to school entry.

II. THE HUMAN PAPILLOMAVIRUS VACCINE

A. *The Introduction of the Human Papillomavirus Vaccine*

On June 8, 2006, the FDA approved Gardasil, a vaccine produced by Merck Pharmaceuticals, to protect against four strands of HPV: types six, eleven, sixteen, and eighteen.¹⁰ HPV strands sixteen and eighteen cause approximately seventy percent of cervical cancers,¹¹ while HPV strands six and eleven may cause genital warts.¹²

entering sixth grade with a medical exemption only. H.B. 2835, 87th Leg., Reg. Sess. (W.V. 2007), available at http://www.legis.state.wv.us/Bill_Text_HTML/2007_SESSIONS/RS/BILLS/hb2835%20intr.htm. The National Conference of State Legislatures tracks bills involving HPV vaccination for all fifty states on its website. National Conference of State Legislatures, <http://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited Jan. 15, 2009).

⁸ See *Zucht v. King*, 260 U.S. 174, 175 (1922); *Jacobson v. Massachusetts*, 197 U.S. 11, 12 (1905).

⁹ *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 12–13 (1973).

¹⁰ FDA, *supra* note 3.

¹¹ Eileen F. Dunne et al., *Prevalence of HPV Infection Among Females in the United States*, 297 JAMA 813, 813 (2007).

While Gardasil protects women against these four HPV strands, there are over a hundred other strands of HPV for which Gardasil does not protect women against and thus even vaccinated women can develop cervical cancer.¹³ Approximately four thousand American women die every year of cervical cancer.¹⁴ While even one death from cervical cancer that is preventable is tragic, comparatively few women die of cervical cancer in contrast to many other diseases.¹⁵

Despite the relative infrequency of cervical cancer, HPV is quite common.¹⁶ Nearly half (44.8%) of women between the ages of twenty and twenty-four have HPV.¹⁷ For females between fourteen and nineteen, the rate of HPV is 24.5%.¹⁸ Even though HPV infection is prevalent, most women who contract HPV do not contract cervical cancer.¹⁹ The reasons why HPV leads to cancer only in some individuals is still unknown.²⁰ If women receive regular Pap smears, however, precancerous lesions can be detected and cancer avoided in most instances.²¹ Despite the fact that regular Pap smears may lessen the risk that a female will contract cervical cancer, the only way Gardasil will effectively protect her from most cervical cancers is for her to be vaccinated before she becomes sexually active.²²

While clinical trials demonstrate that Gardasil is highly effective in protecting against those four HPV strands,²³ there are some cave-

¹² *Id.*

¹³ CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 2.

¹⁴ Estimated deaths from cervical cancer in 2008 are 3870 with 11,070 new cases estimated to be reported. National Cancer Institute, Cervical Cancer, <http://www.cancer.gov/cancertopics/types/cervical> (last visited July 9, 2008).

¹⁵ In contrast, 41,316 Americans died of breast cancer in 2004, and 27,013 died of chronic liver disease or cirrhosis. Arialdi M. Minino et al., *Deaths: Final Data for 2004*, Centers for Disease Control, National Vital Statistics Report 30, 40 (2007), http://www.cdc.gov/nchs/data/nvsr/nvsr55/nvsr55_19.pdf.

¹⁶ By age fifty, approximately eighty percent of American women will have contracted some form of HPV. Bridget M. Kuehn, *CDC Panel Backs Routine HPV Vaccination*, 296 JAMA 640, 641 (2006).

¹⁷ Dunne et al., *supra* note 11, at 813.

¹⁸ *Id.*

¹⁹ Mark H. Schiffman & Philip Castle, *Epidemiologic Studies of a Necessary Causal Risk Factor: Human Papillomavirus and Cervical Neoplasia*, 95 J. NAT'L CANCER INST. E2 (2003), available at <http://jnci.oxfordjournals.org/cgi/content/full/95/6/E2>.

²⁰ *Id.*

²¹ George F. Sawaya et al., *Current Approaches to Cervical Cancer Screening*, 344 NEW ENG. J. MED. 1603, 1606 (2001).

²² Lauri E. Markowitz, M.D., *HPV Vaccines—Prophylactic, Not Therapeutic*, 298 JAMA 805, 805 (2008).

²³ See L.L. Villa et al., *High Sustained Efficacy of a Prophylactic Quadrivalent Human Papillomavirus Types 6/11/16/18 L1 Virus-Like Particle Vaccine Through Five Year Follow-Up*, 95 BRITISH J. CANCER 1459, 1459–66 (2006); see also The Future II Study Group,

ats. First, Gardasil will prevent only cervical cancer if administered prior to a woman coming into contact with HPV, and many women in the studies had HPV despite receiving the vaccination.²⁴ Second, the first of the two comprehensive studies of the vaccine to be released followed women for only three years.²⁵ The second, larger study also showed efficacy at three years.²⁶ However, only a small number of women were tracked for five years,²⁷ and no studies have yet been released following women for longer than five years.²⁸ Third, the tests were performed only on females who were between ages eleven and twenty-six.²⁹ No studies have been released regarding males or regarding females in other age groups.³⁰ Fourth, both major studies, FUTURE I and FUTURE II, were paid for by Merck, Gardasil's manufacturer, who had a monetary interest in positive results.³¹ Outcomes

Effect of Prophylactic Human Papillomavirus L1 Virus-Like Particle Vaccine on Risk of Cervical Intraepithelial Neoplasia Grade 2, Grade 3, and Adenocarcinoma in Situ: A Combined Analysis of Four Randomised Clinical Trials, 369 THE LANCET 1861, 1863 (2007). Both major studies showing Gardasil's efficacy were paid for by its manufacturer, Merck. *Id.* at 1864; Villa et al., *supra*, at 1462.

²⁴ George F. Sawaya & Karen Smith-McCune, *HPV Vaccination: More Answers, More Questions*, 356 NEW ENG. J. MED. 1991, 1991-93 (2007). Over three years, 3.6% of women who received Gardasil in the FUTURE II study developed genital lesions, while 4.4% of women in the placebo group developed such lesions. *Id.* at 1992. This means that 129 females would need to be vaccinated to prevent a single instance of lesions. *Id.*

²⁵ The FUTURE I study consisted of 5455 women. Suzanne M. Garland, M.D., et al., 356 NEW ENG. J. MED. 1928, 1928 (2007). It lasted three years and was double-blind, randomized, and placebo-controlled. *Id.* Efficacy of the vaccine at three years was shown to be ninety-five percent. *Id.* The FUTURE II study was also a double-blind, randomized, placebo-controlled study. The Future II Study Group, *supra* note 22, at 1862. A few of these women were visited again at five years and remained seropositive. *Id.* Only 241 women were still followed at five years, although none had developed HPV. Villa et al., *supra* note 22, at 1461-63.

²⁶ FUTURE II consisted of 20,583 women from the Americas, Europe, and Asia-Pacific. Future II Study Group, *supra* note 22, at 1862. All had fewer than five sexual partners and were followed for at most three years. *Id.* The study showed ninety-nine percent efficacy. *Id.* at 1865.

²⁷ Sawaya & Smith-McCune, *supra* note 24, at 1991-93.

²⁸ *Id.* This time frame may be compared to studies of Varivax, Merck's vaccine protecting against chickenpox, in which 1114 children were followed for ten years. MERCK & CO., INC. VARIVAX: VARICELLA VIRUS VACCINE LIVE 2 (2001) http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf.

²⁹ Sawaya & Smith-McCune, *supra* note 24, at 1991.

³⁰ *Id.* at 1991-93. Merck is planning to seek approval from the FDA of Gardasil for boys, even though Gardasil does little to protect boys from disease. Jan Hoffman, *Vaccinating Boys for Girls' Sake?*, N.Y. TIMES, Feb. 24, 2008, at ST.

³¹ Sawaya & Smith-McCune, *supra* note 24, at 1991-93; cf. Alex Berenson, *Study Reveals Doubt on Drug for Cholesterol*, N.Y. TIMES, Jan. 15, 2008, at A1. Merck along with Schering Plough conducted studies on Vytorin, a drug designed to protect heart health, and changed the goals of the study from greater reduction of heart disease as

are more likely to favor the pharmaceutical manufacturer when the drug study is funded by it as opposed to an independent sponsor of the study.³²

Following these Merck sponsored studies and Gardasil's approval in 2006, many state legislators have proposed laws relating to the vaccine.³³ Because of HPV's prevalence, legislators targeted twelve-year-old girls in order to intervene before they presumably would become sexually active.³⁴ Texas was the first state to require HPV vaccination as a prerequisite to middle school entry, although this was accomplished by Executive Order rather than the Texas legislature enacting a statute.³⁵ Governor Rick Perry's Executive Order required all girls entering the sixth grade to receive HPV vaccination.³⁶ The Order spawned controversy because some among the "religious right" argued that protecting teens from sexually transmitted diseases would encourage them to engage in sexual intercourse.³⁷ Controversy also resulted from Merck's heavy lobbying of Governor Perry prior to his issuance of the Executive Order.³⁸ In response to the furor, Governor Perry rescinded the Order³⁹ and the Texas legis-

compared to other cholesterol medications to reduction of LDL cholesterol when data showed no reduction in rates of heart disease. *Id.* Despite these test results, both pharmaceutical companies aggressively marketed Vytorin as a heart disease medication. *Id.*

³² See Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BRITISH MED. J. 1167 (2003). Lexchin analyzed various studies previously conducted showing that industry sponsorship was correlated with positive outcomes. *Id.* at 1167. The researchers determined that there was no indication that industry sponsorship led to poorer quality of study, but that there was systematic bias in analysis of the data and publication. *Id.*; see also Lisa Bero et al., *Factors Associated with Findings of Published Trials of Drug-Drug Comparisons: Why Some Statins Appear More Efficacious Than Others*, 4 PLOS MED. 1001 (2007), available at http://medicine.plosjournals.org/archive/1549-1676/4/6/pdf/10.1371_journal.pmed.0040184-L.pdf. A University of California at San Francisco study showed that clinical trials of statins had outcomes more favorable to the industry when industry-sponsored. *Id.* at 1005. Industry sponsored trials favored the test drug fifty-seven percent of the time, while government sponsored trials favored the test drug forty-three percent of the time, and trials which did not disclose the sponsor favored the test drug thirty-nine percent of the time. *Id.*

³³ See *supra* note 7.

³⁴ Markowitz, *supra* note 22, at 805.

³⁵ Tex. Exec. Order No. RP65, 2007 Tex. Reg. 8339 (Feb. 16, 2007).

³⁶ *Id.*

³⁷ Robert T. Garrett, *Opposition Mounts to Perry's HPV Order*, DALLAS MORNING NEWS, Feb. 7, 2007, at 3A.

³⁸ *Id.*

³⁹ Christy Hoppe, *Legislature Defeats HPV Mandate, Perry*, DALLAS MORNING NEWS, May 9, 2007, at 1A.

lature passed a law stating that HPV vaccination cannot be a requirement of school enrollment.⁴⁰

Virginia is the only state whose legislature has passed a law mandating the vaccine.⁴¹ Virginia's statute requires girls to receive the first of three separate doses before entering sixth grade.⁴² When the HPV vaccination requirement was first passed, the only permissible exemptions were the same religious exemptions permitted for other required vaccinations.⁴³ The Virginia vaccination statute was amended, altering the vaccination requirement for girls entering the sixth grade after October 2008:

Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.⁴⁴

A bill was pending in Virginia's Senate that, had it passed, would have removed HPV from Virginia's vaccination schedule.⁴⁵ In addition to the Virginia statute, Washington, D.C. has an ordinance requiring that girls entering sixth grade provide either documentation that they have received the HPV vaccine or a letter from their parents indicating that they do not wish to provide the vaccine to their daughters.⁴⁶

At least thirteen other states have proposed legislation mandating HPV vaccination, though no other jurisdiction has yet enacted such a requirement.⁴⁷ Notably, all of these proposals have some form of religious exemption. Some of the proposals allow for exemptions for any reason.⁴⁸ Five other states had mandatory vaccination bills that died in their legislatures.⁴⁹

⁴⁰ TEX. EDUC. CODE ANN. § 38.001 (Vernon 2007). This statute also requires information regarding HPV vaccination be made available to parents. *Id.*

⁴¹ VA. CODE ANN. § 32.1-46 (2007).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ VA. CODE ANN. § 32.1-46(D)(3) (2007).

⁴⁵ S.B. 722, 2008 Reg. Sess. (Va. 2008).

⁴⁶ D.C. CODE ANN. § 7-1651.04 (2007).

⁴⁷ See sources cited *supra* note 7; see also National Conference of State Legislatures, HPV Vaccine, <http://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited Feb. 7, 2008).

⁴⁸ Virginia allows a religious exemption unless an emergency or epidemic is declared. VA. CODE ANN. § 32.1-46 (2007). Washington, D.C. provides an exemption if a parent believes the vaccine would violate religious or medical beliefs, or for any reason with a letter from the parent or guardian. D.C. CODE ANN. § 7-1651.04 (2007). In terms of the proposed legislation, Kansas allows for religious exemption.

While the states have an important interest in the health of their children, specifically that their daughters are protected against HPV, there are better ways to accomplish this goal than mandatory vaccination. Various state legislatures are considering bills promoting vaccination against HPV without making it mandatory. The Arizona legislature has proposed to start a fund to pay for the vaccine for women between the ages of twenty-one and twenty-six, to raise money for education on HPV, and to require that insurance companies cover the vaccine for their female customers.⁵⁰ South Dakota had an initiative where it provided HPV vaccination to any female between the ages of eleven and nineteen who wanted to be vaccinated during 2007.⁵¹ Other state legislatures, such as Montana's, have proposed setting up a task force to explore the issue.⁵² New Jersey's legislature passed a law to distribute information about HPV infection and vaccination to seventh through twelfth grade students and their parents.⁵³ These programs are more respectful of parental rights and inadequacies in scientific data than bills proposing mandatory vaccination.

H.B. 2227, 82nd Leg., Reg. Sess. (Kan. 2007). Michigan and Minnesota would require signed parental statements. H.B. 4164, 94th Leg., Reg. Sess. (Mich. 2007); H.B. 4104, 94th Leg., Reg. Sess. (Mich. 2007); S.B. 243, 85th Leg., 1st Reg. Sess. (Minn. 2007); West Virginia would allow only a medical exemption. H.B. 2835, 87th Leg., Reg. Sess. (W.V. 2007). Vermont H.B. 256 allows religious or moral exemptions. H.B. 256, 2007–2008 Leg. Sess. (Vt. 2007).

⁴⁹ Colorado Senate Bill 80 was postponed and would have forbidden any female over the age of twelve from attending any school in Colorado unless she presented evidence of HPV vaccination. S.B. 80, 66th Gen. Assem., 1st Reg. Sess. (Co. 2007). Parents were required to receive information on the subject and after receiving such information could elect for their daughters to not receive the vaccine. *Id.* Florida Senate Bill 660 died in committee. S.B. 660, 110th Reg. Sess. (Fla. 2007). Maryland Senate Bill 54 was withdrawn. S.B. 54, 422nd Gen. Assem., 2007 Reg. Sess. (Md. 2006). Mississippi House Bill 895 died in committee but had required vaccination to enter sixth grade. H.B. 895, Reg. Sess. (Miss. 2007). South Carolina House Bill 3136, titled the "Cervical Cancer Prevention Act," required female students enrolling in seventh grade to receive vaccination and provided for a religious exemption. H.B. 3136, 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007). Arkansas Senate Bill 954 was withdrawn but would have instituted a program to provide HPV vaccination to each girl over the age of twelve. S.B. 954, 86th Gen. Assem., Reg. Sess. (Ark. 2007).

⁵⁰ S.B. 1385, 49th Leg., 1st Reg. Sess. (Ariz. 2007); S.B. 1437, 48th Leg., 1st Reg. Sess. (Ariz. 2007); and S.B. 1502, 48th Leg., 1st Reg. Sess. (Ariz. 2007).

⁵¹ 2007 S.D. Sess. Laws chapter 201; South Dakota Department of Health, <http://doh.sd.gov/HPV/default.aspx> (last visited Jan. 2, 2009).

⁵² S.B. 505, Reg. Sess. (Mont. 2007).

⁵³ N.J. STAT. ANN. § 18A:40–42 (West 2007).

B. Possible Medical Consequences of Requiring the HPV Vaccine

Proposals for mandatory HPV vaccination have created controversies for a variety of reasons, including the moral ramifications of protecting girls from a sexually transmitted disease and medical concerns about a new therapy. In spite of these disagreements, shortly after Gardasil was approved, Merck began a now-discontinued lobbying campaign to persuade states to mandate HPV vaccination.⁵⁴ Unlike state mandated vaccines in the past that have prevented childhood diseases—some comparatively benign such as chickenpox and others deadly such as polio—the HPV vaccine prevents cancer many years in advance of the cancer’s development. Hence, the risk of contracting cancer many years in the future must be weighed against dangers from administration of the vaccine.

A downside, however, is that the administration of the HPV vaccine contains potential dangers, including seizures, blood clots,⁵⁵ and Guillain-Barré syndrome,⁵⁶ a serious disease that causes severe muscle weakness and paralysis, and may occasionally result in death.⁵⁷ Latent side effects may also arise, perhaps years in the future.⁵⁸ Vaccine safety data is collected primarily around adverse reactions that occur soon after the vaccine is administered and does not necessarily reflect reactions to vaccination that could occur many years in the future.⁵⁹ Thus, any latent side effects may not be included in Gardasil’s safety information, even if they are conclusively proven. Furthermore, studies have not been conducted showing overall health outcomes of children who received vaccines compared to those who have not.⁶⁰ As more vaccines, including Gardasil, are introduced, the increasing toxic load could adversely affect children’s immune systems.⁶¹

In the future, it may be discovered that HPV vaccination is not beneficial. Medical science is constantly changing, and therapies that

⁵⁴ Saul & Pollack, *supra* note 1.

⁵⁵ JOHN ISKANDER, IMMUNIZATION SAFETY OFFICER, CENTERS FOR DISEASE CONTROL AND PREVENTION, QUADRIVALENT HUMAN PAPILLOMAVIRUS (HPV4): UNITED STATES POST-LICENSURE SAFETY UPDATE 6 (2007), <http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jun07/35-hpv3-iskander.pdf>.

⁵⁶ ROBERT W. SEARS, *THE VACCINE BOOK: MAKING THE RIGHT DECISION FOR YOUR CHILD* 181 (2007).

⁵⁷ *Id.* at 181.

⁵⁸ See generally Gary Taubes, *Do We Really Know What Makes Us Healthy?*, N.Y. TIMES MAGAZINE, Sept. 16, 2007 at 52, 80. For example, drug companies promoted hormone replacement therapy for women as beneficial only to find out it had deadly side effects. *Id.* at 53.

⁵⁹ SEARS, *supra* note 56, at 167.

⁶⁰ See *id.*

⁶¹ *Id.*

were accepted by the medical establishment in the past may not be proper today. This is particularly true regarding women's health issues.⁶² Many middle-aged women received hormone replacement therapy on their doctors' advice.⁶³ It was later discovered that the therapy actually increased the risk of cardiovascular disease and breast cancer and should not have been prescribed for many of the women who received the treatment.⁶⁴ Additionally, Vioxx was prescribed for many years before being pulled from the market after the discovery that it increased the risk of heart attacks and strokes.⁶⁵

Given the lack of numerous and long-term studies of the HPV vaccine, the government should not yet require that an entire generation of girls receive the vaccine until it can prove that the vaccine is safe. What should be a slow, methodical process⁶⁶ that permits time for long-term studies to be performed and scrutinized is being cut short in the rush for mass vaccination.⁶⁷ Because few women were followed for more than three years in compiling safety data on Gardasil,⁶⁸ the odds of latent side effects being detected in the future, after clinical trials have concluded, is greater than for other vaccinations. Additionally, Gardasil has not been on the market long enough to gather post-approval safety information.⁶⁹ The consequence is that medical uncertainties which might otherwise be discovered hang over users of Gardasil like the sword of Damocles.

While the potential statutes mandating vaccination surely have the laudatory motive of reducing the incidence of cervical cancer in the United States, there may be medical consequences that the bills' authors are not taking into account. Ironically, a mandate for girls to receive the HPV vaccine before entering school may in fact ultimately lead to girls receiving *fewer* vaccines than if states decline to mandate. The following example illustrates this possibility. In some states parents may receive an exemption from vaccination only if based on religious opposition to vaccinations in general.⁷⁰ In many of these states once a child receives a single vaccination his or her parents

⁶² See Taubes, *supra* note 58, at 53.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ See generally Carrie A. Roll, Comment, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*, 10 J. HEALTH CARE L. & POL'Y 421 (2007).

⁶⁷ Saul & Pollack, *supra* note 1.

⁶⁸ Villa et al., *supra* note 23, at 1463.

⁶⁹ Sawaya & Smith-McCune, *supra* note 24, at 1993.

⁷⁰ Sean Coletti, Comment, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1373-74 (2004).

cannot exempt the child from other vaccinations.⁷¹ As the number of religious exemptions received is increasing nationwide, some officials theorize that many parents seek religious exemptions when in fact they do not want their children to receive vaccinations for non-religious reasons, such as fear of autism resulting from vaccine additives.⁷² Many parents may object to Gardasil for reasons extending from or reaching beyond their fears of other vaccinations.⁷³ These parents may get religious exemptions from all vaccinations in order to avoid giving their daughters Gardasil.⁷⁴ Consequently, the ultimate effect of mandatory HPV vaccination could potentially be a resurgence of other, deadly illnesses as a result of more girls not receiving *any* vaccinations.⁷⁵

Another reason it is too soon to mandate HPV vaccination is that GlaxoSmithKline has developed Cervarix, a vaccine similar to Merck's Gardasil,⁷⁶ which has been approved for use in the European Union and Australia⁷⁷ but has not yet been approved for use in the United States by the FDA.⁷⁸ If HPV vaccination is mandated prior to FDA approval of GlaxoSmithKline's vaccine, an informed decision regarding which vaccine to administer is removed from the physician and patient's control. The cost of HPV vaccination may decrease after Cervarix is introduced to the American market and there is competition for customers between Merck and GlaxoSmithKline. There are medical differences between the two vaccines, as well. Cervarix protects only against HPV strands sixteen and eighteen, which cause cer-

⁷¹ *Id.*

⁷² Steve LeBlanc, *Faith in Vaccines Flags; Parents Claim Religious Exemptions to Avoid Laws*, CHI. SUN TIMES, Oct. 18, 2007, at 30.

⁷³ R. Alta Charo, *Politics, Parents, and Prophylaxis: Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905, 1907 (2007).

⁷⁴ For example, in New Jersey, once a student receives one vaccine, the student may not claim a religious exemption against other vaccinations. See Coletti, *supra* note 75 at 1341.

⁷⁵ If the HPV vaccine is mandated, state health departments could be forced to pay for the expensive vaccine and funding could be diverted from other immunization and public health measures, leading to poor children receiving *fewer* vaccinations overall. See Gail Javitt, Deanna Berkowitz & Lawrence Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 392 (2008).

⁷⁶ *GlaxoSmithKline Initiates Head-to-Head Study of Cervical Cancer Vaccines*, VACCINE WEEKLY, Feb. 21, 2007, at 9.

⁷⁷ *Id.*

⁷⁸ *E.U. Approves New Cervical Cancer Vaccine*, WASH. POST, Sept. 24, 2007, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/09/24/AR2007092400624.html>. Cervarix was slated for FDA approval in early 2008, but the FDA delayed its approval. Elena Berton, *Glaxo Cancer-Drug Approval Delayed*, Wall St. J., Dec. 18, 2007, at D3.

vical cancer; and unlike Gardasil, Cervarix does not offer protection from genital warts.⁷⁹ However, Cervarix may provide higher antibody levels and immune memory response than Gardasil.⁸⁰

Beyond the unknowns from the limited clinical trials are other, policy-based fears.⁸¹ One of these fears is that receiving the HPV vaccination will result in girls either having sex or having unprotected sex, believing themselves to be safe from contracting sexually transmitted diseases.⁸² This fear may be unfounded, but regardless of whether it is realistic, it could cause a backlash against vaccination or education regarding HPV.⁸³ Another, more realistic, fear is that girls who receive the vaccination will fail to get Pap smears, believing themselves immune from cervical cancer, even though the vaccine does not protect women against approximately thirty percent of cervical cancers.⁸⁴ There are many medical reasons why parents might rationally decide to forgo giving the HPV vaccination to their daughters at this time. With such uncertainty about the long-term public health effects of mandatory HPV vaccination, state governments should not require HPV vaccination.

III. THE HPV VACCINE DOES NOT FIT INTO THE PRIOR LEGAL FRAMEWORK REGARDING VACCINATIONS

A. *Cases Upholding Mandatory Vaccination Are Distinguishable from HPV Vaccination*

Two United States Supreme Court cases from the turn of the twentieth century are still widely cited by courts around the nation in

⁷⁹ GlaxoSmithKline, Cervarix, Patient Information Leaflet, <http://www.gsk.com> (last visited July 11, 2008). The fact that Cervarix protects only from cancer and not from genital warts (as Gardasil does) may, paradoxically, make it a more attractive choice to some parents. Parents may believe that because Cervarix is protecting their children only from cancer and that it is thus not likely to encourage their children to engage in premarital sex. See Rebecca E. Skov, *Examining Mandatory HPV Vaccination for All School-Aged Children*, 62 FOOD & DRUG L.J. 805, 812 (2007).

⁸⁰ *GlaxoSmithKline Initiates Head-to-Head Study of Cervical Cancer Vaccines*, *supra* note 75, at 9. In response to Cervarix's possible advantages over Gardasil, GlaxoSmithKline is conducting a study comparing the two drugs and has said it will announce the results whether favorable to Cervarix or not. *Id.*

⁸¹ A study of U.S. physicians has shown that while ninety-seven percent believe that the HPV vaccine should be administered, only forty-three percent believe it should be mandated by the government. *Mandate for Sex? Doctors in the US Speak Out About Mandating the HPV Vaccine*, VACCINE WEEKLY, Apr. 11, 2007, at 12.

⁸² Charo, *supra* note 73, at 1907.

⁸³ *Id.* Studies have not shown condom distribution to teenagers to increase sexual activity even in the face of threats such as teen pregnancy and HIV. *Id.*

⁸⁴ Sigrid Fry-Revere, *The Rush to Vaccinate*, N.Y. TIMES, Mar. 25, 2007, § 14 at 9.

justifying mandatory vaccination as a prerequisite to school entry: *Jacobson v. Massachusetts*⁸⁵ and *Zucht v. King*.⁸⁶ While they are widely used to justify interference with parental rights in requiring vaccination, their meanings have been distorted from the original precedent set in the cases. The precedent laid down in these two cases should not apply to the HPV vaccine, because both cases were decided in response to early vaccination laws which were enacted in reaction to deadly smallpox epidemics.⁸⁷

Smallpox was highly contagious, airborne, and could wipe out entire communities.⁸⁸ Despite the huge dangers from smallpox there was widespread public fear of vaccination.⁸⁹ This was largely because some outbreaks of smallpox were particularly mild, combined with a fear of injecting harmful substances into the body.⁹⁰ It was in this context that the Supreme Court of the United States, in *Jacobson v. Massachusetts*,⁹¹ upheld a Massachusetts law permitting municipalities to require their residents, both adults and children, to be vaccinated against smallpox.⁹² The Court looked at the dangers to the other members of the community if a towns person refused to be vaccinated and determined that vaccination could be mandated to protect the community as a whole from scourge.⁹³ The Court held that vaccination was part of the state's police power in protecting the general welfare.⁹⁴ In its decision, the Court cited the dangers resultant from smallpox, both in the numbers of people who could potentially be infected and the deadly nature of the smallpox virus.⁹⁵

The holding in *Jacobson* was extended to permit mandatory smallpox vaccination as a prerequisite to school attendance in *Zucht v. King*.⁹⁶ Both the *Jacobson* and *Zucht* opinions concerned highly dangerous smallpox transmission.⁹⁷ These two cases are still regularly

⁸⁵ 197 U.S. 11 (1905).

⁸⁶ 260 U.S. 174 (1922); see also *Wright v. Dewitt Sch. Dist. No. 1*, 385 S.W.2d 644, 647 (Ark. 1965); *Cude v. State*, 377 S.W.2d 816, 819 (Ark. 1964).

⁸⁷ See JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 34 (2006).

⁸⁸ *Id.*

⁸⁹ ARTHUR ALLEN, *VACCINE: THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER* 313 (2007).

⁹⁰ *Id.* at 78–79.

⁹¹ 197 U.S. 11 (1905).

⁹² *Id.* at 27.

⁹³ *Id.* at 37.

⁹⁴ *Id.* at 28.

⁹⁵ *Id.* at 33 n.†.

⁹⁶ 260 U.S. 174, 175–77 (1922).

⁹⁷ 197 U.S. at 12.

cited in decisions regarding public vaccination,⁹⁸ but distinctions may be drawn between the mandates at issue in those cases and newer vaccination laws.

Jacobson was decided in reference to adults, as well as children, who faced imminent death without vaccination.⁹⁹ In addition, in both *Jacobson* and *Zucht*, the individuals who declined to be vaccinated endangered the lives of many members of entire communities.¹⁰⁰ In the era in which the Court decided *Jacobson*, thirty percent of the unvaccinated population who came into contact with a particularly deadly strand of smallpox, *variola major*, died as a result.¹⁰¹ This is in contrast to HPV, which is not an airborne illness and kills far fewer Americans than smallpox did at the turn of the century.¹⁰²

As medical science advanced during the twentieth century, vaccination policy turned from smallpox immunity, as discussed in *Jacobson*, to eradicationism during the 1960s¹⁰³ when it became policy that diseases such as measles should be eliminated completely from the population.¹⁰⁴ State governments' motivation for requiring children's vaccinations expanded from preventing the spread of lethal diseases, such as smallpox and polio, to monetary savings resulting from parents not having to miss work in order to care for their children sick with such diseases as measles and chickenpox.¹⁰⁵ While these additional vaccines included protection against terrible scourges such as polio,¹⁰⁶ they also eventually began to include vaccines against diseases that are considered by many to be childhood nuisances, such as chickenpox.¹⁰⁷ Courts continued to use the Supreme Court's decisions in *Jacobson* and *Zucht*, regarding vaccination against smallpox, to

⁹⁸ See, e.g., *Maricopa County Health Dept. v. Harmon*, 750 P.2d 1364, 1369–70 (Ariz. Ct. App. 1987) (upholding mandate for measles vaccination to enter public school in absence of any measles outbreak); *Bd. of Educ. of Mountain Lakes v. Maas*, 152 A.2d 394, 403 (N.J. Super. Ct. App. Div. 1959) (upholding state's requirement that children of Christian Scientist receive immunization against diphtheria and smallpox in the absence of outbreaks of either disease in years while citing *Jacobson* and *Zucht*).

⁹⁹ *Jacobson*, 197 U.S. at 33 n.†.

¹⁰⁰ *Id.*

¹⁰¹ ALLEN, *supra* note 89, at 71.

¹⁰² See ALLEN, *supra* note 89 at 88. The number of estimated deaths from cervical cancer for 2008 is 3870, with 11,070 new cases estimated to be reported. National Cancer Institute, Cervical Cancer, <http://www.cancer.gov/cancertopics/types/cervical> (last visited Aug. 31, 2008).

¹⁰³ See COLGROVE, *supra* note 87, at 149.

¹⁰⁴ *Id.*

¹⁰⁵ ALLEN, *supra* note 89, at 313.

¹⁰⁶ *Id.* at 162.

¹⁰⁷ *Id.* at 313.

uphold mandatory vaccination for diseases that are less deadly and/or less common than smallpox.¹⁰⁸

States began to add vaccines that are largely for self-protection, such as against tetanus and Hepatitis B, to their vaccination schedules as well.¹⁰⁹ This demonstrates how the states have become more expansive in requiring vaccination and have changed their focus from protecting the community to protecting children. Despite the fact that these vaccines protect against illnesses that cannot be caught by attending school with an individual who carries the illness, courts cited *Zucht* in upholding these vaccination requirements.¹¹⁰

The background in which the HPV vaccine could be mandated is far different from the background that led the Supreme Court to uphold mandatory vaccination in *Jacobson* and *Zucht*. In fact, in *Jacobson* the Court looked toward the rights of other members of society to remain free from illness and upheld the law as applying to adults.¹¹¹ The mandatory vaccination was not upheld to support paternalistic government influence but to protect society as a whole from scourge. *Jacobson* and *Zucht* are still relevant in the modern context for diseases that are airborne and highly dangerous¹¹² but should not be interpreted as permitting any and all vaccinations.¹¹³ The Supreme Court case law upholding mandatory vaccination should not be used to permit HPV vaccination, even though courts have cited it in upholding mandatory vaccination against other immunizations that are required primarily for self-protection.

¹⁰⁸ See, e.g., *Maricopa County Health Dept. v. Harmon*, 750 P.2d 1364, 1369–70 (Ariz. Ct. App. 1987); *Cude v. State*, 377 S.W.2d 816, 818 (Ark. 1964).

¹⁰⁹ See, e.g., N.J. ADMIN. CODE §§ 8:57-4.10 to -4.16 (2007).

¹¹⁰ *Cude*, 377 S.W.2d at 819.

¹¹¹ *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905).

¹¹² *Jacobson* and *Zucht* are more analogous to the theoretical discovery of a vaccine against bird flu where requiring immunization of entire communities might save thousands of lives and might be essential to maintaining the health of the community.

¹¹³ Cf. George J. Annas, *Blinded by Bioterrorism: Public Health and Liberty in the 21st Century*, 13 HEALTH MATRIX 33, 56 (2003) (arguing that *Jacobson* is irrelevant to modern society in which Americans have greater rights to medical freedom than in the early twentieth century). *Contra* Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1754–55 (2008) (arguing that HPV is “highly contagious” and, thus, falls under the rubric articulated by the *Jacobson* Court, and proposing narrower exemptions from the broad opt-outs in the current proposed legislation in order to protect more lower-income girls from HPV).

B. Current Exemptions from Vaccinations Insufficiently Protect Parental Rights

As the number of vaccinations that many states require students to receive has increased, states have increasingly permitted parents to exempt their children from such mandates. Many of the proposed statutes mandating HPV vaccination permit parents to exempt their daughters from HPV vaccination using a more lenient standard for exemption from HPV than from other vaccinations.¹¹⁴ Most of the bills requiring HPV vaccination simply require a parent or guardian to sign a letter acknowledging receipt of information regarding HPV and declining to give the vaccine to his or her daughter.¹¹⁵ These “special” exemptions are still insufficient to counter the potential invasion of parental rights given that as more states enact legislation requiring HPV vaccination, the statutes may not all include a “special” exemption.

If legislation is passed requiring girls to receive the HPV vaccination to attend school, without the easier, special exemption, parents may have a difficult time removing their daughters from the HPV requirement.¹¹⁶ Two states, Missouri and West Virginia, currently allow vaccination exemptions for medical reasons only.¹¹⁷ A bill pending in West Virginia that would require HPV vaccination for school entry permits only medical exemptions and does not contain any language indicating the possibility of broader exemptions for HPV vaccination than for other immunizations.¹¹⁸ States that mandate HPV vaccination could potentially see a parental backlash as daughters are vaccinated over parents’ firm objections.

All states other than Missouri and West Virginia permit religious exemptions,¹¹⁹ although how states apply their religious exemptions

¹¹⁴ See *supra* note 48 and accompanying text.

¹¹⁵ See, e.g., H.B. 2835, 87th Leg., Reg. Sess. (W.V. 2007).

¹¹⁶ The ease with which an exemption may be obtained under most of the proposed legislation demonstrates that perhaps even the legislators pushing for vaccination realize that HPV does not fit the model for mandatory vaccination. If the legislators really believe the vaccination is vital to the public health, then they would make an exemption more difficult to receive, as it is for most other vaccinations. That legislators drafted HPV vaccination laws with broad, easy to receive exemptions adds further credence to the idea that the government is interfering with parental autonomy and the vaccine should not be mandated.

¹¹⁷ Welcome to the Website for the Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, <http://www.vaccinesafety.edu/cc-exem.htm> (last visited Feb. 7, 2008).

¹¹⁸ H.B. 2835, 78th Leg., Reg. Sess. (W.Va. 2007), available at http://www.legis.state.wv.us/Bill_Text_HTML/2007_SESSIONS/RS/BILLS/hb2835%20intr.htm.

¹¹⁹ *Id.*

varies widely. Many of these states permit exemption only for members of religions with accepted tenets that oppose vaccination in general.¹²⁰ Some courts have held that the government cannot delve into the sincerity of the parents' beliefs.¹²¹ Yet other courts have ruled that the belief does not need to be a tenet of a "recognized religion," just sincerely held.¹²²

Parties that oppose HPV vaccination on religious grounds may do so because of fears of promiscuity resulting from vaccination against sexually transmitted diseases rather than a religious objection to vaccination in general.¹²³ This may be cast as a moral objection as opposed to a religious objection. Thus, even in states with religious exemptions, parents opposed to HPV vaccination may not be able to exempt their daughters from the vaccine.¹²⁴ The United States District Court for the Eastern District of New York held that a religious exemption only exempts those whose opposition extends from religious views, not "medical or purely moral considerations."¹²⁵ Hence, if parents' desire for a religious waiver stems from fear the vaccine will promote sexual activity rather than religious opposition to the generalized notion of vaccines, their daughters may be required to receive the vaccine despite religious opposition.

If the parents cannot couch their opposition to HPV vaccination in religious terms, they may not be able to exempt their daughters. Over half the states in the nation do not permit philosophical exemptions.¹²⁶ Twenty-seven states do not have philosophical exemptions for parents opposed to vaccination for personal views that are not religious in nature, including opposition to vaccination because of chi-

¹²⁰ See, e.g., *Sherr v. Northport–East Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 94 (E.D.N.Y. 1987) (declining to enjoin school from waiving its vaccination requirements for child of Christian Scientist parents whose beliefs are not "sincerely held").

¹²¹ See, e.g., *Dep't of Health v. Curry*, 722 So. 2d 874, 878 (Fla. Dist. Ct. App. 1st Dist. 1998).

¹²² See, e.g., *Dalli v. Bd. of Educ.*, 267 N.E.2d 219, 222 (Mass. 1971) (broadening Massachusetts's religious exemption to include all beliefs that were religious in nature because giving preference to organized religion was found to be a First Amendment violation).

¹²³ See Charo, *supra* note 73, at 1907.

¹²⁴ See *Farina v. Bd. of Educ. of New York*, 116 F. Supp. 2d 503, 513 (S.D.N.Y. 2000) (declining to grant religious exemption because parents' beliefs were based on medical rather than religious concerns even though parents testified their concerns were religious in nature).

¹²⁵ *Sherr*, 672 F. Supp. at 94.

¹²⁶ Welcome to the Website for the Institute for Vaccine Safety, Vaccine Exemptions, Johns Hopkins Bloomberg School of Public Health, <http://www.vaccinesafety.edu/cc-exem.htm>.

ropractic ethics,¹²⁷ which contend that putting substances into the body is always harmful. An Ohio court ruled that chiropractic ethics should not receive the same heightened deference as religious beliefs would under the First Amendment.¹²⁸ The court thus upheld the vaccination requirement as achieving the legitimate goal of children's safety despite the parents' firmly held beliefs because the beliefs were philosophical and not religious in nature.¹²⁹

This means that parents who object to vaccinating their daughters for such varied reasons as believing vaccination promotes teenage sex, opposing vaccination due to chiropractic ethics, or medical concerns regarding injecting their daughters with a vaccine in which long-term test results have not been released, may not be able to exempt their daughters from the vaccination. Given the multitude of reasons parents may not want their children to receive the HPV vaccine, the laws regarding exemptions are too strict in many jurisdictions.

Additionally, states do not have to permit exemptions for members of religions whose tenets oppose vaccination. In *Employment Division v. Smith*,¹³⁰ the Supreme Court held that an individual's religious beliefs do not excuse him or her from adhering to a valid law that is of general applicability.¹³¹ Thus, under First Amendment free exercise jurisprudence states could require a vaccination for all children as long as the requirement applies to everyone and is otherwise

¹²⁷ See, e.g., N.J. ADMIN. CODE § 8:57-4.4(a) (2008):

A child shall be exempted from mandatory immunization if the parent or guardian objects thereto in a written statement submitted to the school, preschool, or child care center, signed by the parent or guardian, explaining how the administration of immunizing agents conflicts with the pupil's exercise of bona fide religious tenets or practices. General philosophical or moral objection to immunization shall not be sufficient for an exemption on religious grounds.

¹²⁸ *Hanzel v. Arter*, 625 F. Supp. 1259, 1262 (S.D. Ohio 1985).

¹²⁹ *Id.* at 1265-66. The court held that philosophical beliefs do not receive the First Amendment deference awarded to religious beliefs and that a philosophical belief in chiropractic ethics does not fall under Ohio's exemption for "good cause." *Id.* The court upheld the vaccination requirement since philosophical beliefs are not covered under the free exercise clause and thus receive only rational basis review. *Id.* See also *Mason v. Gen. Brown Cent. Sch. Dist.*, 851 F.2d 47, 54 (2d Cir. 1988) (declining to exempt a child from vaccination because chiropractic ethics are "unprotected scientific beliefs"; thus, the child's chiropractor parents did not have constitutional standing to sue for infringement of protected rights). Even religious exemptions may no longer receive more than rational basis scrutiny as a result of the Supreme Court's decision in *Employment Division v. Smith*, 494 U.S. 872 (1990). See *infra* notes 137-144 and accompanying text.

¹³⁰ 494 U.S. 872 (1990).

¹³¹ *Id.* at 879.

valid.¹³² Application of a medical requirement of general applicability in the face of religious beliefs has been upheld in states requiring genetic screening of newborns, even over their parents' objections.¹³³ For instance, genetic testing can determine if a baby has phenylketonuria, a disease which causes severe mental retardation unless discovered and treated when the child is still newborn.¹³⁴ In 2005, the Supreme Court of Nebraska heard *Douglas County v. Anaya*, in which the parents did not want their newborn daughter to receive genetic testing because the testing violated their religious beliefs.¹³⁵ The court held that the state has an interest in children's health that outweighs the parents' religious beliefs.¹³⁶ The court further held that the law was of general applicability and applied to all parents regardless of their religious beliefs, due to the imminent danger to their children.¹³⁷

Therefore, under the First Amendment, vaccinations such as HPV could be required for children even in the face of religious opposition. Despite the fact that all but two states permit some form of religious exemption, they have no federal constitutional burden requiring them to allow religious exemptions. Therefore, exemption law is insufficient to protect against government overreaching. While parents may not have a First Amendment right to refuse vaccination for their children, they do have parental rights to make decisions on raising their children.

¹³² *Id.* at 878–79.

¹³³ See, e.g., *Douglas County v. Anaya*, 694 N.W.2d 601 (Neb. 2005) (upholding Nebraska law requiring genetic testing of newborns as applied to children whose parents are opposed to the testing due to their religious beliefs, under rational basis review because it is a law of general applicability and the state has an interest in preventing disease). Currently all states require such genetic testing. Francy E. Foral, Note, *Necessity's Sharp Pinch: Parental and States' Rights in Conflict in an Era of Newborn Genetic Screening*, 2 J. HEALTH & BIOMEDICAL L. 109, 110 (2006). Two allow for exemptions for any reason, and thirty-three states allow religious exemption only. *Id.* At least six states require parental consent before performing the tests. *Id.*

¹³⁴ Foral, *supra* note 133, at 112.

¹³⁵ *Douglas County*, 694 N.W.2d at 604.

¹³⁶ *Id.*

¹³⁷ *Id.* at 608; see also *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1140–41 (D. Neb. 2006) (holding that genetic testing may be required within seven days of the child's birth, even though testing so soon after birth violates the Scientology belief in silent birth).

IV. THERE IS A PARENTAL RIGHT TO MAKE HEALTH CARE DECISIONS FOR CHILDREN IN MOST CIRCUMSTANCES, AND THIS RIGHT INCLUDES WHETHER TO VACCINATE AGAINST HPV

The parental right to make decisions regarding child rearing should include the decision whether to give girls the HPV vaccine. Parents have a constitutional right to make decisions regarding the raising of their children that should extend to a decision whether to administer the HPV vaccine. In *Troxel v. Granville*,¹³⁸ the Supreme Court of the United States held that a state government needs a more compelling reason to interfere with parental rights than the fact that the state official is making a “better” decision than the parent.¹³⁹ Parents have a fundamental right under the due process clause of the Fourteenth Amendment to make choices regarding their children’s upbringing.¹⁴⁰ This right to make parental decisions should supersede the government’s interest in the public health when, in contrast to *Zucht*,¹⁴¹ a parent’s decision is not likely to imperil other students. In *Zucht*, failure to vaccinate could have led to the imminent deaths of other students in the school as a result of the unvaccinated minor’s attendance at school.¹⁴² With HPV vaccination, other students at the school cannot contract HPV by attending class with a girl whose parents opted out. Parents who decline to provide the HPV vaccine may not be making the “best” decision for their daughters, but such a choice is not a poor enough decision that the state should interfere.

Even though parents have a right to make decisions for their children as established by the Court in *Troxel*,¹⁴³ the government may override the parents’ decision if that decision could result in irreparable harm to their children. In contrast to *Troxel*, which articulated

¹³⁸ 530 U.S. 57 (2000). The Court held that Oregon cannot require children to visit with their grandparents above their mother’s objection simply because government officials decided this was a better decision for rearing the children. *Id.* at 72; 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 parental rights to not enroll their children in school).

¹³⁹ *Troxel*, 530 U.S. at 68–69.

¹⁴⁰ *Id.* at 72–73.

¹⁴¹ *Zucht v. King*, 260 U.S. 174, 175 (1922).

¹⁴² *Id.*; see also *COLGROVE*, *supra* note 87, at 34 and accompanying text.

¹⁴³ See also *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 534–35 (1925) (holding that state law requiring parents to send their children to public school was unconstitutional as violating parents’ right to raise their children as they see fit); *Meyer v. Nebraska*, 262 U.S. 390, 403 (1923) (holding that a state law prohibiting the teaching of foreign languages in Nebraska schools was unconstitutional because it denies parents the right to make decisions regarding how to raise their children).

parents' rights to raise their children, in *Prince v. Massachusetts*,¹⁴⁴ the Court upheld a law that interfered with parental autonomy in order to protect the health of children.¹⁴⁵ Justice Rutledge, writing for the Court, stated, "The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."¹⁴⁶ The Court went on to note that "[p]arents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."¹⁴⁷

Courts have cited *Prince* as a basis for overriding a parent's decision to deny medical treatment for his or her children due to religious beliefs.¹⁴⁸ However, failure to provide a daughter with the HPV vaccine is not "martyring" her. Interference in parental decisions about vaccines should be limited to the standard set forth in *Prince*, as it has been applied with respect to parental decisions regarding medical care other than vaccines. When the state gets involved in requiring medical care over a parent's objections, for issues other than vaccination, it is usually because of grave danger to the child or to protect other children.

For example, an Ohio appellate court ordered that a sick child receive chemotherapy over an objection based on his parents' religious beliefs as Christian Scientists.¹⁴⁹ The court held that the parents' right to refuse medical treatment for themselves for religious reasons did not extend to their son when refusing treatment would "martyr" him.¹⁵⁰ While states have intervened for the "best interests"

¹⁴⁴ 321 U.S. 158 (1944).

¹⁴⁵ *Id.* at 170 (upholding enforcement of a child labor law against parents who argued that religious freedom exempted their children from the law and their young children could be employed proselytizing for Jehovah's Witnesses).

¹⁴⁶ *Id.* at 166-67.

¹⁴⁷ *Id.* at 170.

¹⁴⁸ 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 opposed to blood transfusions as Jehovah's Witnesses and who was at risk for severe brain damage but not death in the absence of a blood transfusion); *Tennessee v. Hamilton*, 657 S.W.2d 425, 429 (Tenn. Ct. App. 1983) (ordering chemotherapy for a girl that was unlikely to save her life but would alleviate her pain in contravention of her parents' religious beliefs).

¹⁴⁹ *In re Willmann*, 493 N.E.2d 1380, 1390 (Ohio Ct. App. 1986). Christian Scientists tend to rely on the power of prayer to heal and not take medicine. See Christian Science Board of Directors, Frequently Asked Questions About Christian Science, <http://www.christianscience.com/questions-christian-science-faq.html> (last visited Dec. 14, 2009).

¹⁵⁰ *Willman*, 493 N.E.2d at 1390.

of newborns or to prevent “martyring” of older children, HPV does not fit within this framework because failure to provide the vaccine will not lead to imminent harm. A teenage girl may circumvent HPV through avoiding sex. Even if she contracts HPV, she may escape from the scourge of cervical cancer by obtaining regular Pap smears. A common thread in cases where medical treatment is ordered over parental objections is an unavoidable, imminent danger. The states’ interest in interfering with parental decision-making for HPV vaccination is far less than for essential treatments, such as chemotherapy or genetic testing.

Besides risk to a child who is forgoing treatment, another instance where courts may intervene over a parent’s objection to medical treatment is when there is a risk to other members of the community if the child remains untreated. HPV does not fit into this model either because vaccination against HPV is solely for the protection of the individual, not to protect the girl’s classmates. An example that illustrates this is *In re J.J.*¹⁵¹ where the Court of Appeals for Ohio’s Twelfth District ordered treatment for a child’s sexually transmitted disease over the parent’s objection.¹⁵² In the case, a fourteen-year-old boy contracted gonorrhea, and he and his mother refused treatment.¹⁵³ The court held, “[w]hile it is true that an adult can refuse medical treatment on religious grounds, the law does not grant a similar right to a juvenile.”¹⁵⁴ In reaching its decision, the court looked at the fact that J.J. had a sexually transmitted disease and was sexually active.¹⁵⁵ Thus, the court noted that without treatment the minor was placing his classmates at risk for contracting gonorrhea.¹⁵⁶

In re J.J. has some parallels to HPV. Both HPV and gonorrhea are sexually transmitted diseases, and in both instances the people involved are teens who may not be particularly responsible regarding safe sex practices. The state government in *In re J.J.* and state legislators proposing mandatory HPV vaccination are attempting to stop the spread of sexually transmitted diseases.¹⁵⁷ *In re J.J.* may be distinguished from HPV vaccination, however, because J.J. was a fourteen-year-old boy with active gonorrhea, while the vaccine would be re-

¹⁵¹ *In re J.J.*, 582 N.E.2d 1138 (Ohio Ct. App. 1990) (per curiam).

¹⁵² *Id.* at 1141.

¹⁵³ *Id.* at 1139.

¹⁵⁴ *Id.* at 1141.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *In re J.J.*, 582 N.E.2d at 1141.

quired for twelve-year-old girls who may or may not carry HPV, and may or may not be sexually active and thus apt to spread HPV. In addition, the court ordered treatment in *J.J.* to protect other students, while HPV vaccination is for self-protection.

If a child is not immediately imperiled and there is little danger to other members of the community, courts tend to decline to override a parent's decision.¹⁵⁸ In a case involving surgery for a cleft palate, the Court of Appeals of New York declined to order treatment because the child could decide on his own after he turned eighteen to undergo surgery to fix his chin.¹⁵⁹ Similarly, the Pennsylvania Supreme Court declined to order spinal fusion surgery for a child with paralytic scoliosis.¹⁶⁰ The child was unable to walk or stand up, but his parents were Jehovah's Witnesses and the surgery would require blood transfusions.¹⁶¹ The court held that death was not imminent, and unless the boy was immediately imperiled, the parents' rights outweighed the state's interest.¹⁶² In both of these cases, the courts noted the lack of imminent need for action. Likewise, a girl who has not received the vaccine can decide to be vaccinated on her own once she turns eighteen. While vaccinating a girl before she is sexually active is the safest route to protecting her from certain HPV strands, given the current medical uncertainties regarding the vaccination and the fact that either the parents or the daughter could decide in the future for her to be vaccinated, the parents' rights supersede the state's interest here as well.

Courts also tend to defer to parents if the medical science is unclear. This judicial deference to parental rights is more widely invoked for medical care when a therapy is new and not widely tested. For example, the Colorado Supreme Court declined to intervene when parents refused to treat their son's epileptic seizures with anti-seizure medication.¹⁶³ The Court referenced medical uncertainty about whether the boy's life was in danger and about potential side

¹⁵⁸ *In re Seiferth*, 127 N.E.2d 820, 823 (N.Y. 1955); *In re Green*, 292 A.2d 387, 392 (Pa. 1972); *In re Tuttendario*, 21 Pa. D. 561, 563 (Pa. Quar. Sess.1912) (declining to order surgery to cure boy's rickets because his parents had the right to make the decision on whether to operate and there is no guarantee the boy would survive the surgery)

¹⁵⁹ *Seiferth*, 127 N.E.2d at 823.

¹⁶⁰ *Green*, 292 A.2d at 392.

¹⁶¹ *Id.* at 388. It is against the tenets of the Jehovah's Witness faith to accept blood transfusions as they are considered unholy. See Watch Tower Bible and Tract Society of Pennsylvania, *The Blood that Really Saves Lives*, http://www.watchtower.org/e/hb/article_05.htm (last visited Jan. 14, 2009).

¹⁶² *Green*, 292 A.2d at 392.

¹⁶³ *People ex rel. D.L.E.*, 614 P.2d 873, 874 (Colo. 1980).

effects from the drug in reaching its decision.¹⁶⁴ Similarly, a girl's life is not likely to be in peril because of a parent's decision not to provide her with Gardasil, and there are medical qualms and side effects that could result from Gardasil's administration. The parental right to make child-rearing decisions should supersede the governmental interest in regard to vaccination, as it does in other medical dilemmas for which there are medical uncertainties.

Courts have also, on occasion, overridden parental decisions simply because a better one could be made, but the government in general should not interfere unless there is an imminent risk to the child.¹⁶⁵ Even if state involvement in such a matter is constitutional, it is not prudent as courts should not be making complicated medical decisions unless there is a dire need to overrule a parent's decision. *Troxel* suggests that requiring medical procedures because a doctor recommends them, and not because of significant dangers to the children without them, violates a parent's fundamental rights.¹⁶⁶

HPV vaccination involves a "better" decision as discussed in *Troxel*.¹⁶⁷ Vaccination against a sexually transmitted disease may be a good decision, but failing to provide such a vaccination does not contain the level of risk present in cases where courts intervene to protect children from imminent, grave danger. This right to make medical decisions for one's children should include the decision about whether to vaccinate against HPV.

V. CONCLUSION

States can require some vaccination even though parents have the right to make medical decisions for their children. However, states should not interfere with parental rights unless there is imminent, grave danger to the individual child or to the population due to communicability of the disease.¹⁶⁸ These are the same circumstances

¹⁶⁴ *Id.*; See also *Newmark v. Williams*, 588 A.2d 1108, 1118 (Del. 1991) (declining to intervene in parent's decision to give child with lymphoma chemotherapy because doctors only gave a forty percent chance of success and the treatment would be painful).

¹⁶⁵ See, e.g., *In re Karwath*, 199 N.W.2d 147, 150 (Iowa 1972) (ordering six children to have their tonsils removed over their father's objection). This case may actually demonstrate why courts should not get involved. Given what has been discovered in the interim about the disease fighting capabilities of tonsils, the father may have actually been medically correct as well as acting within his parental rights, in refusing to remove his children's tonsils.

¹⁶⁶ See *Troxel v. Granville*, 530 U.S. 57, 73 (2000).

¹⁶⁷ *Id.*

¹⁶⁸ A May 2008 Harvard Law Review student note suggested a two-tier system for states to use in requiring students' vaccinations. Note, *Toward a Twenty-First-Century*,

in which the state may vaccinate an adult above his or her objections. One prominent example of the state requiring vaccination for adults is *Jacobson v. Massachusetts*.¹⁶⁹ The Court held the vaccination requirement was constitutional because it was designed to protect the health and safety of other members of the community from the scourge of smallpox.¹⁷⁰ States should be free to require vaccination in response to a deadly scourge or highly contagious epidemics as occurred with smallpox in *Jacobson*.¹⁷¹ For diseases such as HPV that are not airborne illnesses and can be avoided in ways other than vaccination, parents should retain their authority to make decisions for their children just as they have that authority over their own bodies. The state should not require vaccination for children unless it could also require the same vaccination for an adult.¹⁷²

121 HARV. L. REV. 1820, 1841 (2008). If there is a “medical necessity,” for such reasons as deadly outbreaks, as in *Jacobson*, the states could unequivocally require the vaccination, but if there is only a “practical necessity” (the disease is only likely to affect a small subset of the population), the state could still mandate the vaccine but should include a liberal opt-out. *Id.* Another student comment argued that while it is constitutionally permissible for a state to mandate the HPV vaccine, it is not prudent due to the outstanding medical uncertainties. Tracy Solomon Dowling, Note and Comment, *Mandating a Human Papillomavirus Vaccine: An Investigation into Whether such Legislation is Constitutional and Prudent*, 34 AM. J.L. & MED. 65, 83 (2008).

¹⁶⁹ 197 U.S. 11, 39 (1905).

¹⁷⁰ *Id.* Vaccination is not mandatory for adults, as part of the general population, but there is speculation regarding a potential vaccine protecting adults against addiction. M. Susan Ridgely & Martin Y. Iguchi, *Coercive Use of Vaccines Against Drug Addiction: Is it Permissible and is it Good Public Policy?*, 12 VA. J. SOC. POL'Y & L. 260, 262 (2004). Ridgely and Iguchi propose that convicted criminals who are drug addicts could potentially be required to receive such a vaccine to protect the public from crime. *Id.*

¹⁷¹ *Jacobson*, 197 U.S. at 12.

¹⁷² State courts in general have upheld a privacy right for competent adults to refuse medical treatment when there is little risk of harm to other members of the community. See *Suenram v. Soc'y of the Valley Hosp.*, 383 A.2d 143, 148 (N.J. Super. Ct. Law Div. 1977) (holding that patient has privacy right under the New Jersey state constitution that precludes officials from forcing her to receive life-saving cancer treatment); *In re Yetter*, 62 Pa. D. & C.2d 619, 623 (Pa. Comm. Pl. 1973) (federal constitutional right to privacy as established in *Roe v. Wade* includes the right of a competent adult to refuse medical treatment). The Supreme Court has suggested that a liberty interest exists under the due process clause of the Fourteenth Amendment of the U.S. Constitution for a competent adult to refuse life saving treatment. *Cruzan v. Missouri Dep't of Health*, 497 U.S. 261, 267 (1990). The Court has not yet decided a case regarding whether those who are not competent, such as the mentally ill or children, have the right to refuse life saving treatment. The government may require treatment if refusing treatment may lead to grave danger to others. See *Washington v. Harper*, 494 U.S. 210, 227 (1990) (holding that prison officials could force an inmate to take psychiatric medication against his will because of the special safety concerns present in the prison environment, “if the inmate is dangerous to himself or others and the treatment is in the inmate’s medical interest”).

Parents make many decisions every day regarding their children's health that states will not interfere with, such as serving them sugar-laden sodas or letting them watch too much television. States do not get involved every time a "better" parenting decision may be made, and they should not continue to interfere in parental decision-making regarding vaccinations unless there is a risk of harm to others because the parent failed to vaccinate his or her child. *Jacobson* is about the need to protect society, not the individual, and should only be used as a basis for upholding mandatory vaccination when the vaccine is necessary for all members of society, adult and child.

Legislators perhaps fear that parents will not invest the time and money unless the vaccine is mandated. If so, taking the route chosen by South Dakota, and offering free vaccinations, is a positive option to promote women's health.¹⁷³ Laws, such as New Jersey's, requiring schools to provide information on HPV and the vaccine to students and their parents¹⁷⁴ are the best options. Providing a state's citizens information on new medical breakthroughs is more respectful of their rights than requiring administration of a new, inadequately tested vaccination.

States should not continue to get involved in mandating vaccines for which they have no long-term data and for diseases that are not highly contagious. The case law should not be interpreted so broadly to allow any potentially beneficial vaccines to be required for school entry. The scientific landscape has changed dramatically since 1905, when *Jacobson v. Massachusetts* was decided. States could not constitutionally require adults to receive the HPV vaccination because HPV does not pose the risk of imminent harm that could easily spread among entire communities.¹⁷⁵ For future vaccination laws, states should not require any vaccine as a prerequisite for school entry that they could not require adults to receive under their police powers. If the vaccination is not vital enough to be required for all of the state's citizens, states should distribute information to parents rather than impose a paternalistic mandate. To do otherwise is to trample upon parental rights.

¹⁷³ South Dakota Department of Health. <http://doh.sd.gov/HPV/default.aspx>. (last visited Jan. 2, 2009).

¹⁷⁴ N.J. STAT. ANN. § 18A:40-42 (West 2007).

¹⁷⁵ See *Jacobson*, 197 U.S. at 12.