

NOTE

ETHICAL AND LEGAL ISSUES
ACCOMPANYING LEGISLATION
REQUIRING HPV VACCINATION OF
GIRLS

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INTRODUCTION

On February 2, 2007, Texas Governor Rick Perry issued an executive order requiring all females to receive the newly approved vaccine, Gardasil, before enrollment in the sixth grade.¹ The vaccine is highly effective in protecting against cancer-causing strands of the human papillomavirus (HPV), a vastly widespread virus with deadly ramifications.² In support of the order, the Governor stated

The HPV vaccine provides us with an incredible opportunity to effectively target and prevent cervical cancer. . . . Requiring young girls to get vaccinated before they come into contact with HPV is responsible health and fiscal policy that has

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¹ Liz Austin Peterson, *Texas Gov. Orders Anti-Cancer Vaccine*, WASHINGTONPOST.COM, Feb. 2, 2007, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020201001.html>; TX Exec. Order No. RP65, Relating to the Immunization of Young Women from the Cancer-Causing Human Papillomavirus (Feb. 2, 2007), available at <http://www.governor.state.tx.us/divisions/press/exorders/rp65>.

² Press Release, Merck Pharmaceuticals, Merck's New Cervical Cancer Vaccine, Gardasil, Unanimously Recommended by CDC Advisory Panel for Vaccination of Girls and Women 11 to 26 Years (June 29, 2006) (on file with Health Matrix: Journal of Law-Medicine).

the potential to significantly reduce cases of cervical cancer and mitigate future medical costs.³

Though the vaccine has obvious and substantial benefits, legislation, such as that in Texas, has become quite controversial on a variety of grounds. There are those who object to bypassing the state legislature and issuing an executive order, as Governor Perry did. Additionally, some parents feel that such legislation encroaches on their parental decision-making authority. Still others protest based on issues of safety, access, and cost. Furthermore, there is an argument that legislation requiring the vaccination of only females violates Title IX of the Education Amendments of 1972⁴ and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution.⁵ However, analysis of these issues appears to end in favor of HPV vaccination legislation and, until a similar vaccine is approved for males, the legislation seems to pass statutory and constitutional muster.

I. HPV AND THE GARDASIL VACCINE

The human papillomavirus (HPV) is the most widespread sexually transmitted disease in the United States.⁶ The virus can be spread merely by genital-to-genital contact—no sexual penetration is necessary⁷—and is a significant cause of cervical cancer.⁸ A large drug company, Merck, discussed HPV and its consequences, stating:

In the United States, approximately 20 million people are infected with HPV, and approximately 80 percent of females will have acquired HPV by age 50. For most people, HPV goes away on its own; however, . . . certain high-risk types of HPV, if unrecognized and untreated, can lead to cervical cancer. Cervical cancer is the second most common cause of cancer death in women worldwide, resulting in nearly a half-million diagnoses and 240,000 deaths each year. In addition, certain low-risk types of HPV cause genital warts and can

³ Press Release, Office of the Governor, Gov. Perry Establishes HPV Vaccination Program for Young Women (Feb. 2, 2007), <http://www.governor.state.tx.us/divisions/press/pressreleases/PressRelease.2007-02-02.0949>.

⁴ Education Amendments of 1972, Title IX, 20 U.S.C. § 1681(a) (2000).

⁵ U.S. CONST. amend. XIV § 1.

⁶ TX Exec. Order No. RP65, *supra* note 1.

⁷ See WebMD.com, *Genital Warts (Human Papillomavirus)-Cause*, <http://www.webmd.com/sexual-conditions/hpv-genital-warts/tc/genital-warts-human-papillomavirus-cause> (last visited Nov. 2, 2007).

⁸ See Press Release, Merck Pharmaceuticals, *supra* note 2.

lead to abnormal Pap results. Approximately 1 million cases of genital warts occur each year in the United States and an estimated 32 million cases occur worldwide. Additionally, there are an estimated 4.7 million abnormal Pap results that require follow-up each year in the United States. At least 3 million of these results are caused by some type of HPV. [Furthermore,] HPV related disease, including screening, follow-up[,] and treatment, costs about \$5 billion per year in the U.S.⁹

Thus, the highly contagious nature of HPV and the severity of its effects are a serious issue.

Fortunately, the recent FDA approval of Merck's Gardasil, the first vaccine to prevent the most common types of HPV, marks progress toward alleviating the spread of HPV.¹⁰ The United States Centers for Disease Control and Prevention (CDC) states that Gardasil "protects against four HPV types, which together cause 70% of cervical cancer and 90% of genital warts."¹¹ The vaccine is currently licensed for use in females between the ages of nine and twenty-six and has proven to be almost one hundred percent "effective in preventing diseases caused by the four HPV types covered by the vaccine—including precancers of the cervix, vulva[,] and vagina[] and genital warts."¹² This could potentially save thousands of lives.¹³ However, the effectiveness of the vaccine in males is not yet known, although it is being researched.¹⁴

II. HPV VACCINATION LEGISLATION

In July 2006, immediately after the FDA approved Gardasil, the United States Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) unanimously recommended that females between the ages of eleven and twenty-six

⁹ *Id.*

¹⁰ CDC, HPV Vaccine Questions & Answers, <http://www.cdc.gov/std/hpv/hpv-vaccine.pdf> (last visited Nov. 2, 2007).

¹¹ *Id.*

¹² *Id.*

¹³ Kaisernetwork.org, American Cancer Society Releases Guidelines on Merck's HPV Vaccine Gardasil (Jan. 23, 2007), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=42404 (The American Cancer Society "estimates that 11,150 cervical cancer cases will be diagnosed this year in the U.S. and that 3,670 women will die from the disease.").

¹⁴ CDC, *supra* note 10; Nigel Hawkes, *Male Jab to Reduce Cervical Cancer*, TIMESONLINE, Jan. 23, 2007, http://www.timesonline.co.uk/tol/life_and_style/health/article1295381.ece.

receive Gardasil.¹⁵ ACIP advised that all eleven and twelve year old females be vaccinated, as well as all females thirteen to twenty-six not previously vaccinated, and upon recommendation of their physicians, nine and ten year old females should also be vaccinated.¹⁶ Although the ACIP recommendations do not translate into vaccination requirements by individual states or mandatory insurance coverage, state health authorities and private insurers usually follow the Committee's suggestions.¹⁷ Texas, for one, has followed these recommendations by requiring HPV vaccination,¹⁸ and many other states have similar legislation pending.¹⁹

In February 2007, Texas became the first state to require HPV vaccination.²⁰ Anxious to enact mandatory vaccination requirements, Texas Governor Rick Perry bypassed the state legislature by issuing an executive order requiring Texas schoolgirls to receive the Gardasil vaccination.²¹ The order stipulates that, beginning in September 2008,

¹⁵ CDC, *supra* note 10; See Press Release, Merck Pharmaceuticals, *supra* note 2.

¹⁶ See Press Release, Merck Pharmaceuticals, *supra* note 2.

¹⁷ *Id.*

¹⁸ Peterson, *supra* note 1; Associated Press, *Gov. Perry Under Pressure to Rescind Cervical Cancer Vaccination Order to Protect Girls from HPV*, FOXNEWS.COM, Feb. 5, 2007, http://www.foxnews.com/printer_friendly_story/0,3566,250337,00.html.

¹⁹ Kaisernetwork.org, *supra* note 13

²⁰ Peterson, *supra* note 1; Associated Press, *supra* note 18.

²¹ Peterson, *supra* note 1; TX Exec. Order No. RP65, *supra* note 1, states: WHEREAS, immunization from vaccine-preventable diseases such as Human Papillomavirus (HPV) protects individuals who receive the vaccine; and
WHEREAS, HPV is the most common sexually transmitted infection-causing cancer in females in the United States; and
WHEREAS, the United States Food and Drug Administration estimates there are 9,710 new cases of cervical cancer, many of which are caused by HPV, and 3,700 deaths from cervical cancer each year in the United States; and
WHEREAS, the Texas Cancer Registry estimates there were 1,169 new cases and 391 deaths from cervical cancer in Texas in 2006; and
WHEREAS, research has shown that the HPV vaccine is highly effective in preventing the infections that are the cause of many of the cervical cancers; and
WHEREAS, HPV vaccine is only effective if administered before infection occurs; and
WHEREAS, the newly approved HPV vaccine is a great advance in the protection of women's health; and
WHEREAS, the Advisory Committee on Immunization Practices and Centers for Disease Control and Prevention recommend the HPV vaccine for females who are nine years through 26 years of age;

girls entering the sixth grade will be required to be vaccinated for HPV.²² The Texas state legislature lacks the power to repeal Perry's executive order, so the order is effective until changed by Perry or a successor.²³ The Governor, however, chose to act by executive order because he believes the issue to be of imminent and serious importance.²⁴

Other states and the District of Columbia have introduced legislation similar to that in Texas. As of March 2007, legislation had been introduced in forty-one states and the District of Columbia to "require,

NOW THEREFORE, I, RICK PERRY, Governor of Texas, by virtue of the power and authority vested in me by the Constitution and laws of the State of Texas as the Chief Executive Officer, do hereby order the following:

Vaccine. The Department of State Health Services shall make the HPV vaccine available through the Texas Vaccines for Children program for eligible young females up to age 18, and the Health and Human Services Commission shall make the vaccine available to Medicaid-eligible young females from age 19 to 21.

Rules. The Health and Human Services Executive Commissioner shall adopt rules that mandate the age appropriate vaccination of all female children for HPV prior to admission to the sixth grade.

Availability. The Department of State Health Services and the Health and Human Services Commission will move expeditiously to make the vaccine available as soon as possible.

Public Information. The Department of State Health Services will implement a public awareness campaign to educate the public of the importance of vaccination, the availability of the vaccine, and the subsequent requirements under the rules that will be adopted.

Parents' Rights. The Department of State Health Services will, in order to protect the right of parents to be the final authority on their children's health care, modify the current process in order to allow parents to submit a request for a conscientious objection affidavit form via the Internet while maintaining privacy safeguards under current law.

This executive order supersedes all previous orders on this matter that are in conflict or inconsistent with its terms[,] and this order shall remain in effect and in full force until modified, amended, rescinded, or superseded by me or by a succeeding governor.

²² TX Exec. Order No. RP65, *supra* note 1; Press Release, Office of the Governor, *supra* note 3.

²³ Peterson, *supra* note 1 (stating that "the Texas Constitution permits the governor, as head of the executive branch, to order other members of the executive branch to adopt rules like this one").

²⁴ Press Release, Office of the Governor, *supra* note 3 ("HPV is the most common sexually transmitted disease in the United States. Today, approximately 20 million people in the nation are infected, including one in four 15 to 24 year olds. Certain strains of HPV cause most cases of cervical cancer. Texas has the second highest number of women suffering from this devastating disease in the nation. In 2006, there were 1,169 new cases and nearly 400 deaths from cervical cancer in the state.").

fund, or educate the public about the HPV [v]accine.”²⁵ Twenty-four of those states²⁶ and the District of Columbia have introduced legislation mandating HPV vaccination as a requirement for school enrollment.²⁷ A Washington, D.C. bill would, like Texas, require girls entering sixth grade to receive a HPV vaccination.²⁸ Females would be required to produce proof of vaccination prior to enrollment in sixth grade unless their parents selected to opt out of the requirement.²⁹ Thus, although states appear to be reacting to the ACIP’s recommendations to vaccinate girls,³⁰ some people are objecting to the resulting legislation.

III. OBJECTIONS TO HPV VACCINATION LEGISLATION

Although Merck stated on February 20, 2007 that it “is immediately suspending its lobbying campaign to persuade state legislatures to mandate that adolescent girls get the company’s . . . vaccine as a requirement for school attendance,”³¹ the legislation that already exists and that which is still being considered has invoked various objections. Many are upset with Texas Governor Perry’s bypassing of the state legislature with his executive order.³² Parents are concerned about encroachment on their decision-making authority by this sort of

²⁵ These states include Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and West Virginia. Nat’l Conference of State Legislatures, *HPV Vaccine*, Sept. 20, 2007, <http://www.ncsl.org/programs/health/hpvpvaccine.htm>.

²⁶ These states include California, Colorado, Connecticut, Florida, Georgia, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Missouri, Minnesota, Mississippi, New Jersey, New York, New Mexico, Ohio, Oklahoma, South Carolina, Texas, Vermont, Virginia, and West Virginia. *Id.*

²⁷ *Id.*

²⁸ KaiserNetwork.org, *supra* note 13.

²⁹ *Id.* However, the bill does not indicate under what circumstances an opt-out would be allowed. *Id.*

³⁰ Some states have enacted legislation requiring funding of the HPV vaccine or educating the public about the vaccine (for example, Utah’s legislation establishing “an awareness campaign on the causes, prevention, and risks of cervical cancer”), but Texas is the only state, as of March 2007, to have mandated HPV vaccination. *Id.*

³¹ Associated Press, *Merck Suspends Lobbying for HPV Vaccine to Become Law*, Feb. 20, 2007, <http://www.foxnews.com/story/0,2933,253162,00.html>.

³² Associated Press, *supra* note 18.

legislation in general,³³ in addition to issues of safety, access, and cost. Furthermore, legislation requiring the vaccination of only females presents possible constitutional and statutory issues. Such laws may violate Title IX of the Education Amendments of 1972 and the Equal Protection Clause of the Fourteenth Amendment.

A. General Objections—Bypassing of the State Legislature, Encroachment on Parental Decision-Making, and Issues of Safety, Access, and Cost

Governor Perry's Executive Order in Texas, and any future legislation like it, is coming under attack for various reasons. For one, Texas state legislators are frustrated at the fact that Perry has bypassed the legislature and passed an executive order on his own.³⁴ One state senator complained that the situation was "not an emergency," and, thus, legislators should have been given the opportunity to discuss and debate the issue.³⁵ The Senator contends that testimony from doctors, scientists, and patients was in order before the implementation of such a "sweeping mandate."³⁶

Some parents have also been opposed to the legislation because they feel it encroaches upon their decision-making authority as parents.³⁷ Immediately after Governor Perry issued his executive order, protesting parents flooded the telephone lines.³⁸ Many states, including Texas, allow parents to opt their children out of vaccinations based on religious or philosophical grounds;³⁹ Perry's executive order even seeks to "ease the opt out process" by directing the Department of State Health Services to provide exemption request forms online.⁴⁰ Regardless, many parents remain concerned about the interference with their right to make medical decisions for their children and the burden of filing an affidavit to opt out of the inoculation.⁴¹ Conservative parents, in particular, are concerned because they fear the vaccine

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ Peterson, *supra* note 1.

³⁸ Associated Press, *supra* note 18.

³⁹ In *Brown v. Stone*, the Mississippi Supreme Court held that religious exemptions unfairly threaten all school children's health, but most courts have upheld the constitutionality of religious exemptions. *Brown v. Stone*, 378 So. 2d 218 (1979); PUBLIC HEALTH LAW AND ETHICS 379 (Lawrence O. Gostin ed., 2002).

⁴⁰ Press Release, Office of the Governor, *supra* note 3; TX Exec. Order No. RP65, *supra* note 1.

⁴¹ Peterson, *supra* note 1.

condones premarital sex.⁴² Parents have begun fighting the Texas legislation on these grounds and are likely to fight any similar legislation in other states.⁴³

Historically, safety concerns have been a common objection to vaccination,⁴⁴ and parents may oppose new HPV vaccination requirements on the belief that vaccines, in general, are not safe. For instance, there are those that argue that vaccines are a factor in causing autism,⁴⁵ but numerous reports and the CDC contend there is no truth to such claims. The CDC is adamant that “[t]he weight of currently available scientific evidence does not support the hypothesis that vaccines cause autism.”⁴⁶ The argument linking vaccines to autism relates to the presence of thimerosal, a mercury-containing preservative present in some vaccines.⁴⁷ Thimerosal has been used since the 1930s, but the CDC contends that:

No harmful effects have been reported from thimerosal at doses used in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999, the Public Health Service (PHS) agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.⁴⁸

Gardasil, specifically, contains no thimerosal or mercury; “it is made up of proteins from the outer coat of the virus,” and “[t]here is no infectious material in the vaccine.”⁴⁹ Furthermore, studies have shown that Gardasil has no serious side effects.⁵⁰ Therefore, although there

⁴² Associated Press, *supra* note 18.

⁴³ Peterson, *supra* note 1 (One citizens’ group, Parents Requesting Open Vaccine Education, fought for rights to opt out of other vaccine requirements and is fighting the Texas legislation as well.).

⁴⁴ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 378.

⁴⁵ CDC, Autism and Vaccines Theory, http://www.cdc.gov/od/science/iso/concerns/mmr_autism_factsheet.htm (last visited Nov. 10, 2007); See Kelley Beaucar Vlahos, *Debate Rages Over Vaccine-Autism Link*, FOXNEWS.COM, Apr. 27, 2005, <http://www.foxnews.com/story/0,2933,154556,00.html>; See Anita Manning, *Debate Over Vaccines, Autism Heats Up*, USATODAY, July 20, 2005, at 6D.

⁴⁶ CDC, Autism and Vaccines Theory, *supra* note 45.

⁴⁷ CDC, Mercury and Vaccines (Thimerosal), <http://www.cdc.gov/od/science/iso/concerns/thimerosal.htm>; Vlahos, *supra* note 45.

⁴⁸ CDC, *Mercury and Vaccines (Thimerosal)*, <http://www.cdc.gov/od/science/iso/concerns/thimerosal.htm> (last visited Sept. 20, 2007).

⁴⁹ CDC, *supra* note 10.

⁵⁰ *Id.*

remain objections to vaccines based on safety concerns, such studies confirm the safety of Gardasil and vaccines in general.⁵¹

Another issue involved in HPV vaccination legislation is the question of access to and cost of the vaccine. The retail price of the vaccine is \$120 per dose (\$360 for the entire series, consisting of three doses), and, often, there is a lag time after a vaccine is recommended before it is covered by health plans.⁵² In Texas, however, it does not appear that this is going to be a problem because Governor Perry has directed state health authorities to allow girls between the ages of nine and eighteen who are uninsured or whose insurance does not cover vaccines to have free access to the vaccine.⁵³ Additionally, Perry ordered Medicaid to offer the vaccine to women between the ages of nineteen and twenty-one.⁵⁴ Many other state legislatures that have proposed HPV vaccination legislation have also included various funding measures in the proposals.⁵⁵

On the nationwide level, the ACIP has voted to add Gardasil to the CDC's Vaccines for Children (VFC) program, which, since 1994, has provided vaccines to Medicaid-eligible, uninsured, underinsured, and Native American children.⁵⁶ Over forty-five thousand sites, such as hospitals, public clinics, and private clinics provide VFC vaccines, and some states provide vaccines for little or no cost to people without vaccine health insurance coverage at public health facilities.⁵⁷ Hence, though access and cost may be viewed as a barrier to receiving the vaccine and, thus, as a partial basis for objection to the HPV legislation, these issues do not appear to be legitimate concerns in the implementation of such legislation. In fact, more significant than any of

⁵¹ The CDC states that “[t]he United States currently has the safest, most effective vaccine supply in history. Years of testing are required by law before a vaccine can be licensed. Once in use, vaccines are continually monitored for safety and efficacy.” CDC, Vaccine Safety Information for Parents, http://www.cdc.gov/od/science/iso/general_info/parents.htm (last visited Nov. 2, 2007).

⁵² CDC, *supra* note 10.

⁵³ Associated Press, *supra* note 18; Peterson, *supra* note 1.

⁵⁴ Associated Press, *supra* note 18; Peterson, *supra* note 1.

⁵⁵ For example, Colorado's S.B. 97 “would allocate four percent of state tobacco settlement money to the cervical cancer immunization fund”; Connecticut's H.B. 5485 “would provide coverage of the HPV vaccine through the state's insurance plan”; Georgia's H.B. 11 “would mandate insurance coverage for the vaccine”; Hawaii's H.B. 590 “would require health insurance providers to cover the HPV vaccine”; Iowa H.F. 661 “would require insurance providers to cover the cost of the HPV vaccine for females nine to 26 years of age.” Nat'l Conference of State Legislatures, *supra* note **Error! Bookmark not defined.**

⁵⁶ See Press Release, Merck Pharmaceuticals, *supra* note 2.

⁵⁷ CDC, *supra* note 10.

the above mentioned objections may be the statutory and constitutional issues associated with HPV vaccination legislation, especially if it turns out that males can be vaccinated as well as females but continue to be exempt from the requirement.

B. Statutory and Constitutional Issues with HPV Vaccination Legislation

States' police power to compel vaccinations has been a widely accepted and sanctioned power for many years, primarily on the basis of public health.⁵⁸ Thus, since general vaccination requirements are usually legitimate, the requirement for HPV vaccinations for girls probably is as well. The outcome may change, however, if boys continue to be exempted from the requirement, since the vaccine will likely be effective for them as well. That scenario raises Title IX and equal protection issues.

1. Public Health Issues and the Source of State/Locality Power to Compel Vaccination

Vaccinations have been labeled "among the most cost-effective and widely used public health interventions"⁵⁹ and serve "a long-range goal, which is optimal health for the entire community."⁶⁰ Thus, historically, states and localities have had the power to compel vaccinations based on their mandate to protect public health⁶¹ and, particularly, to require proof of vaccinations for various diseases as a condition of school entry.⁶²

Lawrence O. Gostin, a law professor at Georgetown University and professor of public health at the Johns Hopkins University, argues the importance of public health via vaccination by stating that public health involves "an organized community effort;" it cannot result from "isolated individual efforts."⁶³ One example of effective organized effort is the emergence of smallpox vaccinations, which would not have put a halt to the disease if not for the strategy of communitywide vaccination.⁶⁴

Gostin makes his public-health-via-vaccination argument by invoking Professor Garrett Hardin's famous "tragedy of the commons"

⁵⁸ See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

⁵⁹ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 379 (citation omitted).

⁶⁰ *Id.* at 38.

⁶¹ *Jacobson*, 197 U.S. at 25.

⁶² *Zucht v. King*, 260 U.S. 174 (1922).

⁶³ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 37 (citation omitted).

⁶⁴ *Id.*

argument—the argument that individuals pursuing their own best interests will lead to a “tragedy of the commons.”⁶⁵ As Gostin states it, “if each person is left free to pursue his or her own personal aspirations, the individual may benefit[,] but the population will suffer.”⁶⁶ Thus, Hardin stated that “mutual coercion, mutually agreed upon,”⁶⁷ or, as Gostin phrases it, “coercion through democratic decision making,”⁶⁸ is the solution. “It may be that a parent benefits if his or her child remains unvaccinated because of the risk of adverse effects,” Gostin argues, but “[t]his assumes . . . that there is herd immunity in the population. If enough parents resist vaccination, the population loses herd immunity, resulting in a tragedy of the commons.”⁶⁹

It has been said that public health law actually began with *Jacobson v. Massachusetts*,⁷⁰ when Henning Jacobson refused to comply with a Cambridge, Massachusetts ordinance requiring smallpox vaccination.⁷¹ The Court, in that case, defended “communal values of health and security and exhibit[ed] deference to the legislature and public health authorities.”⁷² The Court did, however, make a “statement of the constitutional limitations imposed on public health authorities” and established four constitutional standards.⁷³ The first standard is public health necessity, meaning public health powers are only exercisable when necessary to avert an avoidable harm.⁷⁴ Secondly, the means to prevent the health threat must be reasonable, that is, they must have a “real or substantial relation” to protecting public health.⁷⁵ A regulation probably would not be considered to be reasonable if it is imposed in such a way that it violates either Title IX of the Education Amendments, as discussed below in Part III.B.2., or the constitutionally mandated equal protection of the laws, as discussed below in Part

⁶⁵ Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968); PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 383.

⁶⁶ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 383.

⁶⁷ Hardin, *supra* note 65, at 1247.

⁶⁸ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 383.

⁶⁹ *Id.*

⁷⁰ 197 U.S. 11 (1905).

⁷¹ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 206.

⁷² *Id.* at 215.

⁷³ *Id.* at 216.

⁷⁴ *Id.* at 216; *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905). There is an argument that HPV vaccination regulations do not meet the necessity prong of the Jacobson standards since individuals acquire HPV through avoidable action, since the virus is not airborne, and since the virus cannot spread via casual contact. By contrast, Hepatitis B vaccinations, for example, are different because, although the virus is a sexually transmitted disease, one can also become infected by non-voluntary means, such as blood transfusions.

⁷⁵ *Jacobson*, 197 U.S. at 31.

III.B.3. Additionally, there must be proportionality.⁷⁶ In other words, the burden imposed by the public health regulation cannot be disproportionate to the expected benefit.⁷⁷ Lastly, the regulation must avoid undue harm to the subject.⁷⁸ The *Jacobson* Court found that the ordinance compelling smallpox vaccinations met all of these standards, and, thus, since that case, vaccinations have been widely accepted as constitutional assertions of state police power.⁷⁹

Jacobson makes clear that states and localities have the power to compel vaccination, and, another case, *Zucht v. King*,⁸⁰ specifically addressed conditioning school entry on vaccinations requirements.⁸¹ The Court in that case declined to declare unconstitutional a local government mandate requiring vaccination as a prerequisite for attendance in public school.⁸² That decision was based on *Jacobson* and the importance of public health.⁸³ Thus, regulations requiring vaccination as a prerequisite for school attendance, regulations which all states have in place,⁸⁴ are proper uses of state and local police power if those regulations meet the *Jacobson* standards, which they usually do. In the case of the HPV vaccination legislation, however, a question arises as to the reasonableness of the legislation (the second *Jacobson* standard) because the legislation requires that only girls be vaccinated. That distinction in treatment between girls and boys may be a violation of Title IX of the Education Amendments and of the Equal Protection Clause of the Fourteenth Amendment; such violations would probably doom the legislation under the reasonableness prong of the *Jacobson* test.

2. Possible Violation of Title IX of the Education Amendments of 1972

Title IX of the Education Amendments of 1972 states that, absent exceptions, “[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.”⁸⁵ The Department of Educa-

⁷⁶ *Id.*

⁷⁷ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 216.

⁷⁸ *Jacobson*, 197 U.S. 11, 36-37.

⁷⁹ *Id.* at 39.

⁸⁰ 260 U.S. 174 (1922).

⁸¹ *Id.* at 176.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ PUBLIC HEALTH LAW AND ETHICS, *supra* note 39, at 379.

⁸⁵ Education Amendments of 1972, Title IX 20 U.S.C. § 1681(a) (2007).

tion's (DED) Office for Civil Rights, which has been delegated the task of interpreting Title IX,⁸⁶ has stated that "Title IX applies to all public and private educational institutions that receive federal funds, i.e., recipients, including, but not limited to, elementary and secondary schools, school districts, proprietary schools, colleges, and universities."⁸⁷ Nearly all educational institutions receive federal financial assistance, even if through only one program such as a school lunch program,⁸⁸ and *any* federal funding, even if only in one program, brings the educational institution within the purview of Title IX.⁸⁹

Since most schools receive federal funding, it could be argued that legislation compelling only girls to be vaccinated for HPV as a condition for school enrollment is a violation of Title IX because it denies girls participation in school based on sex. Yet, there is no reported case law addressing an issue comparable to legislation requiring only single-sex vaccination as a condition of school attendance, so it is unclear how the Court would analyze such a case. However, *Trent v. Perritt*,⁹⁰ may be relevant to this issue. *Trent* dealt with a male student's claim of discrimination under Title IX based on a high school dress code providing different regulations for boys' and girls' hair.⁹¹ The plaintiff in that case complained that requiring male students, but not female students, to adhere to certain hair styles as a condition of school attendance was a violation of their civil rights.⁹² Because the

⁸⁶ 34 C.F.R. § 106.1, (2007) (stating that the purpose of the regulations "is to effectuate [T]itle IX of the Education Amendments of 1972); *Cohen v. Brown Univ.*, 991 F.2d 888 (1993)(deferring to the Department of Education's Office for Civil Rights' interpretation of Title IX because the legislative history is ambiguous); *see also* Ross A. Jurewitz, *Playing at Even Strength: Reforming Title IX Enforcement in Intercollegiate Athletics*, 8 AM. U.J. GENDER SOC. POL'Y & L. 283, 286-87 (2000)(discussing the ambiguousness of Title IX and its legislative history and the fact that courts have, therefore, deferred to the Department of Education's Office for Civil Rights).

⁸⁷ Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties, 65 Fed. Reg. 66,092, 66,099 (Nov. 2, 2000).

⁸⁸ RUTH COLKER & ADAM A. MILANI, *THE LAW OF DISABILITY DISCRIMINATION* 300 (5th ed. 2005).

⁸⁹ *Cohen*, 991 F.2d at 894 (describing Congress's passage of the Civil Rights Restoration Act of 1987, 20 U.S.C. § 1687, which requires "that if any arm of an educational institution receive[s] federal funds, the institution as a whole must comply with Title IX's provisions).

⁹⁰ 391 F.Supp. 171 (S.D. Miss. 1975).

⁹¹ *Id.* at 171 (The regulation "prohibit[ed] male students from wearing hair below the ear lobe or over the collar.").

⁹² Plaintiffs also alleged a constitutional violation, but that claim was dismissed for failure to state a claim upon which relief could be granted. *Id.* at 171-72. The *Trent* court referred to the holding in *Karr v. Schmidt*, 460 F.2d 609 (5th Cir.

school was a public school that participated in federally funded programs, the plaintiff argued that Title IX prevented the school from discriminating on the basis of sex.⁹³ The court held that the intent of Congress in passing Title IX was to aid female students in gaining skills equivalent to male students rather than to require every student to look alike.⁹⁴ The statute was intended to make federal financial assistance available to girls as much as boys in educational programs, which “does not require that the recipient [of federal funding] erase all differences between the sexes.”⁹⁵ Thus, the court held that the school’s dress code regulations did not rise to the level of a sexual discrimination violation under Title IX.⁹⁶

A similar result is likely in an allegation that female vaccination requirements violate Title IX. Vaccination does not prevent federal funding from being available to girls’ educational programs. The vaccination requirement does not alter the funding of girls’ programs or prevent girls from attaining skills comparable to those which boys attain—safety, access, and cost issues (as discussed in Part III.A. above and mentioned below) do not actually prevent girls from receiving a comparable education, especially considering the opt-out option. Hence, although vaccination is a more serious issue than a dress code, it, nevertheless, seems likely a court would see the vaccination issue, like a dress code, as outside the purview of Title IX.

1972), in its brief discussion of the constitutional claim:

In *Karr v. Schmidt*, . . . the Fifth Circuit was faced with “another of the multitude of lawsuits which have recently inundated the federal courts attacking hair length regulations promulgated by local public school authorities.” In dealing with the question of whether or not there is a constitutionally protected right for a high school student to wear his hair as he pleases, the appellate court concluded that the matter of hair grooming does not rise to the level of a constitutional concern under due process, or of equal protection analysis if the regulation is rationally based to accomplish a permissible state objective, and further that the burden is on the challenger to show that the regulation is arbitrary. The appellate court then went further, holding: “Given the very minimal standard of judicial review to which these regulations are properly subject in the federal forum, we think it proper to announce a *per se* rule that such regulations are constitutionally valid. Henceforth, district courts need not hold an evidentiary hearing in cases of this nature. Where a complaint merely alleges the constitutional invalidity of a high school hair and grooming regulation, the district courts are directed to grant an immediate motion to dismiss for failure to state a claim for which relief can be granted.”

Id. at 172.

⁹³ *Id.* at 172.

⁹⁴ *Id.* at 173.

⁹⁵ *Trent*, 391 F.Supp. at 173.

⁹⁶ *Id.*

Analysis of Title IX cases, generally, also provides some indication of how a court would likely analyze the vaccination requirement. Title IX cases of sexual harassment are analogized to cases of sexual harassment⁹⁷ under Title VII of the Civil Rights Act of 1964,⁹⁸ and Title IX cases of employment discrimination are analogized to Title VII employment discrimination cases.⁹⁹ The DED's Office for Civil Rights has promulgated detailed regulations regarding athletics in the Title IX context,¹⁰⁰ and courts have adhered to those interpretations,¹⁰¹ but there is no indication in case law (other than that mentioned in *Trent* above) or in the Office for Civil Rights regulations of how a court would address the vaccination issue at hand. Other than an analysis similar to that of *Trent*, one can only suppose what a court might consider; the Office for Civil Rights regulations allow for differences in athletic programs for boys and girls provided there is equal athletic opportunity for both sexes.¹⁰² This could be analogized to the vaccination issue by arguing that, because of the vaccine's safety, ease of access, and low cost and because of opt-out provisions in the legislation, requiring females to receive the vaccine does not deprive them of an equal opportunity to attend school. Furthermore, even if a court found there to be an inequality of opportunity to attend school because of the vaccination requirement, the legislation would not be preventing equality of opportunity for the sexes *based on sex*—instead the inequality of opportunity would be for all those who are at present medically eligible for the vaccination, that is, girls.

On the other hand, on-going studies are attempting to determine whether the vaccine prevents HPV in males¹⁰³ (this is discussed more thoroughly in Part III.B.3. below). If the vaccine is effective in males, there will certainly be a case for a Title IX violation if boys are not subsequently obligated to get vaccinated before attending school.

⁹⁷ *Ward v. Johns Hopkins Univ.*, 861 F.Supp. 367 (D.Md. 1994) (“Title IX claims are appropriately analyzed under standards applicable to cases brought under Title VII.”).

⁹⁸ 42 U.S.C.S. §§ 2000e-2000e-15 et seq. (2007).

⁹⁹ *Mabry v. State Bd. of Community Colleges & Occupational Education*, 813 F.2d 311 (1987) (stating that “[c]ourts should turn to [the employment-related sex discrimination under Title VII] case law concerning employment-related discrimination under Title VII for guidance if confronted with employment-related allegation of discrimination under Title IX”).

¹⁰⁰ 34 C.F.R. § 106.41 (2007).

¹⁰¹ *Cohen v. Brown Univ.*, 991 F.2d 888 (1993) (deferring to the Department of Education's Office for Civil Rights' interpretation of Title IX because the legislative history is ambiguous).

¹⁰² 34 C.F.R. § 106.41 (2007).

¹⁰³ CDC, *supra* note 10; *Infra* Section III.B.3.

Researchers think that the vaccine will have health benefits for males, such as preventing genital warts and rare cancers,¹⁰⁴ but whether males will receive any health benefit may not actually be relevant to the question of compelled vaccination because vaccinating boys will have indirect health benefits for girls by preventing the spread of the virus to them. Therefore, there would be no reason to require vaccination for girls alone other than, simply, some sexual bias, in which case, the requirement would be sex-based. Thus, if studies confirm what is thought to be the case, that the vaccine will be effective in males,¹⁰⁵ then any regulation requiring female-only vaccination as a condition for school entry would constitute a Title IX violation, even if the vaccine does not have any independent health benefits for males.

3. Possible Violation of the Equal Protection Clause

The Equal Protection Clause of Fourteenth Amendment of the United States Constitution states that no person shall be denied “the equal protection of the laws.”¹⁰⁶ The Supreme Court has interpreted the Equal Protection Clause to require that, when a law or policy imposes a different standard or burden on one gender, the government must prove an “exceedingly persuasive justification” for that sex-based classification.¹⁰⁷ Texas’s legislation, and similar proposed legislation in other states, obligating only girls to receive an HPV vaccination, could potentially violate the Equal Protection Clause if the legislation has no such exceedingly persuasive justification for its sex discrimination.

*Craig v. Boren*¹⁰⁸ established the standard for evaluating equal protection claims based on gender discrimination. In that case, two males challenged an Oklahoma statute prohibiting the sale of 3.2% beer to males under the age of twenty-one and to females under the age of eighteen.¹⁰⁹ The plaintiffs argued that the statute constituted discrimination against males between the ages of eighteen and twenty in allowing females of those ages to buy the beer, while preventing males of the same age to do so.¹¹⁰ The Court held that, for a gender biased statute to pass constitutional muster, the state had to show that

¹⁰⁴ *Id.*

¹⁰⁵ Hawkes, *supra* note 14.

¹⁰⁶ U.S. CONST. amend. XIV § 1.

¹⁰⁷ *U.S. v. Virginia*, 518 U.S. 515, 534 (1996).

¹⁰⁸ 429 U.S. 190 (1976).

¹⁰⁹ *Id.* at 192.

¹¹⁰ *Id.*

the sex-based classification served an important governmental objective and was substantially related to that objective.¹¹¹ The state's proffered objectives were the prevention of drinking and driving and the enhancement of traffic safety.¹¹² To demonstrate that its objectives were served by the statute, it presented statistics indicating that 2% of males ages eighteen to twenty were arrested for driving under the influence of alcohol, while only .18% of women in that age group were arrested for that offense.¹¹³ Considering the negligible differential between the .18% and 2% and that the statute would not actually prevent males between eighteen and twenty from driving under the influence, since they could have someone else buy the beer for them or simply consume some other sort of alcohol that the statute did not regulate, the Court concluded that gender was not a legitimate and accurate proxy for regulating drinking and driving.¹¹⁴ Therefore, the Court held that the classification was not substantially related to the achievement of an important governmental objective, and, thus, the statute constituted a denial of equal protection of the laws.¹¹⁵

In *U.S. v. Virginia*,¹¹⁶ Justice Ginsburg, writing for the Court, characterized the *Craig* framework for analyzing equal protection based on gender, explaining that a sex-based classification sufficient to pass intermediate scrutiny will have "an exceedingly persuasive justification" that links the means chosen to the state's important objective. The issue in that case was whether Virginia's policy of denying women admission to Virginia Military Institute (VMI), a publicly funded university, was a violation of equal protection.¹¹⁷ Virginia argued that admitting "women would downgrade VMI's stature, destroy the adversative system and, with it, even the school."¹¹⁸ The objectives of maintaining a highly respected, adversarial school are important, but the discriminatory policy was not substantially related to achieving those objectives because Virginia's reliance on overbroad generalizations about differences between men and women did not provide an exceedingly persuasive justification for its discriminatory policy.¹¹⁹ Thus, the Court struck down the policy and held that "the Constitution's equal protection guarantee precludes Virginia from reserving

¹¹¹ *Id.* at 197.

¹¹² *Id.* at 199.

¹¹³ *Id.* at 191.

¹¹⁴ *Craig v. Boren*, 429 U.S. 190, 202-04 (1976).

¹¹⁵ *Id.* at 204.

¹¹⁶ 518 U.S. 515, 534 (1996).

¹¹⁷ *Id.* at 523.

¹¹⁸ *Id.* at 542.

¹¹⁹ *Id.* at 545-46.

exclusively to men the unique educational opportunities VMI affords.”¹²⁰

Like the policies in *Craig* and *Virginia*, any policy requiring females but not males to receive an HPV vaccination before being allowed to enroll in school could constitute an equal protection violation, depending on how the requirement is implemented. The government clearly has an important objective—preventing HPV—because, as discussed in Part I, statistics show that HPV results in many adverse health effects, including cervical cancer. Currently, though the means of achieving the stated objective are discriminatory, they probably *are* substantially related to the objective. The vaccine is highly effective,¹²¹ there is, at present, no approved vaccine for males,¹²² and there is no other method of preventing the spread of HPV besides complete abstinence from *any* sexual activity (not simply abstinence from sex),¹²³ which is unlikely in today’s culture. Additionally, as discussed in Part III.A., safety, access, and cost should not be an obstacle to vaccination.

It could be argued that requiring all girls to be vaccinated, rather than attempting to single out those for whom the risk may be greatest, is simply more effective against the virus, and the Supreme Court has “rejected administrative ease and convenience as sufficiently important objectives to justify gender-based classifications.”¹²⁴ However, it does not seem that administrative ease is the basis for requiring that all girls receive the vaccination. It is important to vaccinate all females because it is likely girls will not even know when they are at risk, since there are often no signs of the virus.

Since there may soon be a male HPV vaccine available, the question arises as to whether the need to vaccinate girls alone is enough now or whether states should wait to require vaccination until both girls and boys can receive the vaccination. Clearly, the sooner anyone is vaccinated, the better, since every vaccination will have diminishing effect on the prevalence of the virus. Therefore, there appears to be a persuasive reason to proceed with single-sex vaccination. Thus,

¹²⁰ *Id.* at 519.

¹²¹ CDC, *supra* note 10.

¹²² *Id.*

¹²³ See WebMD.com, *supra* note 7.

¹²⁴ *Craig v. Boren*, 429 U.S. 190, 198 (1976); See also *Reed v. Reed*, 404 U.S. 71, 76 (1971) (holding that giving “a mandatory preference to members of either sex over members of the other, merely to accomplish the elimination of hearings on the merits,” is unconstitutional); See also *Frontiero v. Richardson*, 411 U.S. 677, 690 (1973) (holding that according differential treatment to males and females for the sole purpose of achieving administrative convenience is unconstitutional).

requiring girls to be vaccinated appears to be substantially related to preventing the spread of HPV, and, given that HPV is a serious virus responsible for many thousands of deaths each year,¹²⁵ there is an exceedingly persuasive justification for imposing upon girls the small burden of getting the injections.

However, the situation would likely change if and when a vaccine for males becomes available. As mentioned in the Title IX discussion, a version of the vaccine for men is presently undergoing testing, and thought to be near approval.¹²⁶ Once a male vaccine is approved, the female-only vaccination requirement might not be substantially related to the objective of preventing HPV because there will be other, more effective means of prevention. Statistics indicate that, if both males and females are vaccinated, more than ninety percent of cases of HPV caused by the four most common strands (those strands the vaccine prevents) would be eradicated, as opposed to only seventy-five percent of HPV cases where only females are vaccinated.¹²⁷ Studies show that “[v]accinating boys as well as girls . . . would greatly increase the number of lives saved.”¹²⁸

Further, if the vaccination requirement is for females only, there would still surely be those who would opt-out, avoid the vaccine, or otherwise remain unvaccinated and would, therefore, remain vulnerable to infection from males. Various factors could cause some females to be at risk to the virus: some females may get an exemption from the vaccine requirement; the vaccine could be ineffective in some; and the vaccine may not be required in every state.¹²⁹ Hence, the vaccine’s effect would be greatly augmented if males are also required to receive the vaccination. The objective of preventing HPV is not well-served by limiting vaccination requirements to females, and,

¹²⁵ See Press Release, Merck Pharmaceuticals, *supra* note 2; Press Release, Office of the Governor, *supra* note 3.

¹²⁶ Hawkes, *supra* note 14.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ For example, in California in 2006, 77.7% of children enrolled in kindergarten received all required immunizations mandated by California law by the age of two. Kids Data, Children with All Required Immunizations: 2006, http://www.kidsdata.org/topictables.jsp?i=1&t=10&ra=3_132&o_id=0&pi=&yr=8&sort=n&nf=1&sh=1&menuused=updateFXT&x=181&y=10 (last visited Apr. 2, 2007). In 2005, Washington had a child immunization rate of about 78%, and, nationwide, roughly 81% of children were completely immunized. Press Release, Wash. State Dep’t of Health, Washington Makes Substantial Gains in Immunization Rates (July 27, 2005), available at http://www.doh.wa.gov/Publicat/2005_news/05-096.htm. These statistics indicate that there is a significant portion of school children not receiving required vaccinations.

therefore, if the vaccine is approved for both sexes, the fit is poor between that objective and discriminatory means of pursuing it. Thus, following approval of the vaccine for males, any policy should be amended to make the vaccine requirement gender neutral, as it would otherwise violate the Equal Protection Clause.

CONCLUSION

Clearly HPV is serious and deadly, but, fortunately, with the approval of Gardasil, a huge advancement has been made toward eliminating the virus. As discussed above, there are those who, for various reasons, object to legislation such as that in Texas, requiring females to receive the vaccine as a condition of school attendance. However, there are strong counterarguments to those objections, and, furthermore, any argument that such legislation violates Title IX of the Education Amendments or the Equal Protection Clause is not likely to succeed unless and until a vaccine is approved for males as well. At such point, there may still be objections based on encroachment on parental decision-making and issues of safety, access, and cost, but there may also be Title IX and equal protection issues such that any mandatory vaccination legislation will have to be gender neutral in order to withstand scrutiny under Title IX and the U.S. Constitution.