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Putting an End to an Unconstitutional Result: Equal Protection and Due Process Analyses of the Requirement that Female Immigrants Receive the Gardasil Vaccine Prior to Becoming Permanent Residents of the United States

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Articles

PUTTING AN END TO AN UNCONSTITUTIONAL RESULT: EQUAL PROTECTION AND DUE PROCESS ANALYSES OF THE REQUIREMENT THAT FEMALE IMMIGRANTS RECEIVE THE GARDASIL VACCINE PRIOR TO BECOMING PERMANENT RESIDENTS OF THE UNITED STATES

Elizabeth R. Sheyn*

I. INTRODUCTION

Imagine that you are a twenty-four-year-old woman who has, despite all the odds, been allowed to emigrate to the United States with your husband. Perhaps you have been granted asylum or have been labeled a refugee. Now imagine that you would like to have the right to work in the United States and to be protected by this country's laws. In order to gain these rights, however, you must apply for and receive either permanent resident status¹ or a "Green Card."² Before August

* J.D., University of Pennsylvania Law School, 2008; B.A., University of Chicago, 2005. This article was written while the author was a law clerk for The Honorable Judge James S. Gwin of the United States District Court for the Northern District of Ohio. For their diligent work on this Article, thanks are due to the staff of the Valparaiso University Law Review. Any errors remaining in the Article are the sole responsibility of the author.

¹ Lawful permanent residents have the right to:

[(1)] live permanently in the United States provided [they] do not commit any actions that would make [them] removable (deportable) under the immigration law (section 237, Immigration and Nationality Act); (2) be employed in the United States at any legal work of [their] qualification and choosing; and (3) be protected by all of the laws of the United States, [their] state of residence and local jurisdictions.

USCIS—Now That You Are a Permanent Resident, <http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnextoid=fe17e6b0eb13d010VgnVCM10000048f3d6a1RCRD&vgnnextchannel=4f719c7755cb9010VgnVCM10000045f3d6a1RCRD> (last visited July 9, 2009).

Permanent residents must (1) "obey all of the laws of the United States, the States, and localities"; (2) file income tax returns and report income to the Federal and State Internal Revenue Services; (3) support the democratic form of government and refrain from attempting "to change the government through illegal means"; and (4) register with the Selective Service if they are males between the ages of 18–25. *Id.* Permanent residents can travel freely outside of the United States and can reenter the country after presenting their green card or Permanent Resident Card, which is Form I-551. *Id.* Permanent residents can only vote in local and state elections that do not require voters to be United States citizens. *Id.*

To maintain permanent resident status, individuals may not:

[(1)] [m]ove to another country intending to live there permanently; (2) [r]emain outside of the US for more than one year without obtaining a reentry permit or returning resident visa; (3) [r]emain

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2008, you would have had to satisfy the same legal and medical requirements as your husband to obtain a Green Card. Currently, however, you—unlike your husband—must receive, over the course of six months, three shots of Gardasil—one of the most expensive and controversial vaccines on the market that is not mandated for female United States citizens.

This Article provides an overview of the development and use of the Gardasil vaccine and examines the problems raised by the requirement that all female immigrants between the ages of eleven and twenty-six who are seeking permanent resident status receive Gardasil vaccinations. In light of the social, economic, and constitutional issues implicated by the use of Gardasil, this Article argues that this vaccine must be reclassified as being an optional, rather than a mandatory part of female immigrants' process of becoming permanent residents and, eventually, United States citizens.³

outside of the US for more than two years after issuance of a reentry permit without obtaining a returning resident visa; (4) [f]ail to file income tax returns while living outside of the US for any period; and (5) [d]eclare [themselves] "nonimmigrant[s]" on [their] tax returns.

Id. Further, permanent residents can be removed or deported if they vote in elections limited to United States citizens. *Id.*

Finally, permanent residents can petition for some relatives (spouses and children regardless of age) to join him or her in the United States as immigrants. *Id.* These relatives may then, in turn, be eligible for permanent residence without needing to file separate petitions. *Id.*

² The Green Card or "Permanent Resident Card, Form I-551, is issued to all [p]ermanent [r]esidents as evidence of alien registration and their permanent status in the US." *Id.* Permanent residents must have and carry a currently valid green card at all times. *Id.* This card remains valid for ten years, although permanent residency status does not expire within ten years. *Id.* Green cards can be used to:

prove employment eligibility in the US when completing the Form I-9 for a new employer. [They] can also be used to apply for a Social Security Card and a state issued driver's license. The card[s] [are] valid for readmission to the United States if the trip was not greater than one year in length. If a trip will last longer than one year, a reentry permit is needed.

Id.

³ Becoming United States citizens is arguably the primary goal of individuals who have emigrated to the United States and who have been granted permanent resident status.

Naturalization is the primary method for most persons not born as US citizens to obtain that status. Under current law naturalization is done by the federal and state courts and in administrative proceedings. Once a permanent resident completes the necessary residence and physical presence requirements (which vary in certain cases), an application for naturalization can be filed with Immigration. This starts a review of the person's basic eligibility, criminal and security histories, and then leads to testing of the person's English language

Part II of this Article lays out the history of the development of the Gardasil vaccine, as well as its usage. Part III addresses the new Centers for Disease Control and Prevention (“CDC”) mandate that female immigrants between the ages of eleven and twenty-six receive a full course of the Gardasil vaccine before they can obtain permanent residency status and, eventually, become naturalized citizens of the United States. Part IV discusses commentators’ and organizations’ social, economic, and cultural arguments against the Gardasil vaccine requirement for immigrant women. Finally, Part V examines the constitutional concerns implicated by the Gardasil vaccine mandate. Section A of Part V questions the constitutionality of the Gardasil requirement under the Equal Protection Clause of the Fourteenth Amendment (also enshrined in the Fifth Amendment), and Section B of Part V evaluates the requirement’s lawfulness under the Due Process Clauses of the Fifth and Fourteenth Amendments.

II. THE GARDASIL VACCINE – ITS DEVELOPMENT AND USAGE

Cervical cancer is one of the major causes of female morbidity and mortality worldwide.⁴ Human papillomaviruses (“HPVs”),⁵ particularly HPV-16 and HPV-18, are responsible for most cervical cancers.⁶ According to the CDC, nearly 20 million Americans are currently infected with a type of HPV and an additional 6.2 million will become infected each year.⁷ Furthermore, “[a]t least 50% of sexually active men and women acquire [a] genital HPV infection at some point in their

abilities, knowledge of the history and form of government of the US, and good moral character.

Id. Naturalized citizens have the same rights and privileges as a native born United States citizen, but only native born United States citizens can be President of the United States. *Id.*

⁴ See THOMAS E. ROHAN & KEERTI V. SHAH, *CERVICAL CANCER: FROM ETIOLOGY TO PREVENTION* xxv (2004).

⁵ See generally *STD Facts—Human Papillomavirus (HPV)*, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm#Whatis> (last visited July 9, 2009) [hereinafter “STD Facts”].

Genital human papillomavirus (HPV) is the most common sexually transmitted infection. The virus infects the skin and mucous membranes. There are more than 40 HPV types that can infect the genital areas of men and women Most people who become infected with HPV do not even know they have it.

Id.

⁶ See The Future II Study Group, *Quadrivalent Vaccine Against Human Papillomavirus to Prevent High-Grade Cervical Lesions*, 356 *NEW ENG. J. MED.* 1915, 1916 (2007) [hereinafter “Future II Study Group”] (“Human papillomaviruses . . . cause virtually all cervical cancers, with HPV types 16 (HPV-16) and 18 (HPV-18) responsible for approximately 70%.”).

⁷ See *STD Facts*, *supra* note 5.

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lives.”⁸ While the body’s immune system can fight off HPV in a majority of cases, the American Cancer Society estimates that in 2009, 11,270 women will be diagnosed with cervical cancer in the United States and 4070 women will die from cervical cancer.⁹ A smaller, but still significant number of women and men will be diagnosed with other HPV-related cancers, such as vulvar, vaginal, penile, and anal cancers.¹⁰

Although preventive measures, such as the Papanicolaou smear (also known as the “Pap smear” or “Pap”),¹¹ have brought about a marked decline in the deaths caused by cervical cancer, overall¹² “such programs are costly and have not been effectively implemented in most developing countries.”¹³ Additionally, while an HPV test can detect the presence of the HPV virus, there is a low probability that the virus will eventually lead to cancer and, as a result, the HPV test is not the optimal cancer-diagnosing tool.

To “prevent cervical cancer, precancerous genital lesions[,] and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18,”¹⁴ Merck & Co., Inc. manufactured a vaccine named Gardasil.¹⁵ After

⁸ *Id.*

⁹ ACS: What Are the Key Statistics About Cervical Cancer?, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_cervical_cancer_8.asp (last visited Oct. 27, 2009).

¹⁰ See STD Facts, *supra* note 5.

¹¹ The Pap smear “is a microscopic examination of cells collected from the uterine cervix.” ROHAN & SHAH, *supra* note 4, at 4. Such an examination can reveal abnormal, precancerous, and cancerous cells, as well as non-cancerous conditions. See The Pap Test: Questions and Answers—National Cancer Institute, <http://www.cancer.gov/cancertopics/factsheet/Detection/Pap-test> (last visited July 9, 2009). There are a variety of “Pap sampling method[s],” and, therefore, “not all Pap smears are equal in their sensitivity, specificity[,] or clinical performance.” ROHAN & SHAH, *supra* note 4, at 5.

¹² See Shannon Brownlee, *Cancer Screening: Doing More Harm Than Good?*, READER’S DIG., Apr. 2009, available at <http://www.rd.com/living-healthy/cancer-screening-and-prevention-news-in-health/article122134.html> (“[O]nly one cancer screening test, the venerable Pap smear, has truly slashed the risk of death. Between 1955 and 1992, according to the American Cancer Society, Pap smears cut the death rate for cervical cancer by 74 percent, and deaths have continued to decline each year.”).

¹³ The Future II Study Group, *supra* note 6, at 1916 (footnote omitted).

¹⁴ Press Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus Rapid Approval Marks Major Advancement in Public Health, (June 8, 2006), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm> [hereinafter “U.S. Food & Drug Admin.”].

¹⁵ GlaxoSmithKline, Merck’s rival, produces a vaccine named Cervarix that works in essentially the same way as Gardasil. See Donald G. McNeil, Jr., *How a Vaccine Search Ended in Triumph*, N.Y. TIMES, Aug. 29, 2006, at F1, available at <http://www.nytimes.com/2006/08/29/health/29hpv.html?scp=6&sq=cervarix&st=cse> (noting that Cervarix produces the same protein as Gardasil, “with the same power, in an insect virus grown in a broth of caterpillar ovary cells”). Although the Advisory Committee for Immunization Practices

a series of studies, the Food and Drug Administration (“FDA”) approved Gardasil for use by females¹⁶ between the ages of eleven and twenty-six¹⁷ in June 2006.¹⁸

(“ACIP”) has given a limited endorsement to the use of Cervarix in the United States as of October 2009, the “CDC still has to adopt the new recommendation for it to become official advice for U.S. physicians.” *Panel Backs Vaccine As Cervical Cancer Alternative*, N.Y. TIMES, Oct. 21, 2009, <http://www.nytimes.com/aponline/2009/10/21/health/AP-US-MED-Cervical-Vaccine.html>. The Cervarix vaccine will be available in the United States in late 2009.

It is unclear whether Gardasil and Cervarix will ultimately be interchangeable, given the limitations of Cervarix. For example, Cervarix targets two types of human papillomavirus while Gardasil targets four types. *See id.* Gardasil also protects against genital warts while Cervarix does not. *Id.* There is a small price difference between the two vaccines, with Cervarix costing about \$5 less than Gardasil for the full course of the vaccine. *Id.*

¹⁶ In December 2008, Merck requested approval from the FDA for Gardasil’s use in vaccinating males. *See* Linda A. Johnson, *Drugmaker Merck Seeks Gardasil Approval for Boys*, THE ASSOCIATED PRESS, Jan. 6, 2009, <http://abcnews.go.com/Business/wireStory?id=6586156>. According to Merck’s spokeswoman, this application was part of Merck’s “strategy to increase the market for Gardasil.” *Id.* With the application, Merck included research data from one of its studies, which included “4,065 males, ages 16–26.” *See* Michelle Fay Cortez & Shannon Pettypiece, *Merck Cancer Shot Cuts Genital Warts, Lesions in Men*, BLOOMBERG, Nov. 13, 2008, <http://www.bloomberg.com/apps/news?pid=20601103&sid=aajzweDaXZh0&refer=us>.

As part of this study, researchers gave each participating male three shots of Gardasil or a placebo, “then tracked them for signs of infection with HPV. After about thirty months, three men getting Gardasil developed genital warts and none had pre-cancerous growths linked to the HPV virus, compared with twenty-eight cases of warts and three pre-cancerous lesions in the placebo group.” *Id.* None of the men had been infected with HPV prior to the beginning of the study. *Id.* A majority of the participating men were heterosexual males. *Id.* Although HPV does not affect men to the same extent as it does women, it “may cause about 1,500 men to develop penile cancer a year and 1,900 to get anal cancer, according to the [CDC].” *Id.* Further, men are considered to be the “key transmitters of HPV to women.” *Id.* Homosexual men, in particular, “have an elevated risk of developing some cancers.” *Id.*

In October 2009, the ACIP concluded that Gardasil “could be given to boys and young men to protect them from genital warts,” after the FDA approved the use of the vaccine for boys and men aged nine to twenty-six. Natasha Singer, *Vaccine Against Virus in Girls May Be Given to Boys*, N.Y. TIMES, Oct. 22, 2009, at A25. The ACIP “stopped short of urging [Gardasil’s] routine use in boys, as it has recommended for girls,” questioning the propriety and cost-effectiveness of vaccinating boys “for a problem that can be embarrassing and uncomfortable but is not life-threatening.” *Id.*

¹⁷ The FDA has, to date, resisted Merck’s request to widen approval of Gardasil’s use to permit women ages twenty-seven to forty-five to receive the vaccine. The FDA has asked Merck “for more information before it decides whether to expand approval for Gardasil.” *FDA Delays Decision on Gardasil Approval for Older Women*, WASH. POST, Jan. 9, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/01/09/AR2009010902027.html>; Johnson, *supra* note 16 (“The agency approved use of Gardasil in females ages 9 to 26 years old in June 2006, but last June rejected expanding that to include women ages 27 to 45.”). This decision is likely linked to a government-funded Harvard study suggesting that the Gardasil vaccine is cost-effective for younger girls but not for women in their twenties.

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Four studies, one American and three multinational, were conducted on 21,000 women to determine the effectiveness of Gardasil (the vaccine or a placebo) in women between the ages of sixteen and twenty-six.¹⁹ The studies “showed that in women who had not already been infected, Gardasil was nearly 100% effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed.”²⁰ Although the duration of the study period was not long enough for cervical cancer to develop, the prevention of cervical precancerous lesions is believed to result in the prevention of cervical cancer.²¹ Two studies also determined that the immune response to the vaccine among younger women ages nine to fifteen was similar to those found in sixteen to twenty-six-year-olds.²² The results of the studies demonstrate that the vaccine is only effective when administered prior to infection; it does not, however, prevent the development of cervical cancer in women who are already infected with some HPV types included in the vaccine.²³

See Jane J. Kim & Sue J. Goldie, *Health and Economic Implications of HPV Vaccination in the United States*, 359 NEW ENG. J. MED. 821, 827 (2008); see also Johnson, *supra* note 16 (“Gardasil had 2007 sales of \$1.5 billion, but sales began slowing in the second half of 2008, after a government-funded Harvard study concluded that it was cost-effective for girls but not for women in their 20s.”); Peter Loftus, *Study Questions Cost-Effectiveness of Gardasil Cervical-Cancer Vaccine*, WALL ST. J., Aug. 21, 2008, at D3.

Gardasil’s cost is justified in pre-adolescent girls, partly because they are less likely to have already been exposed to HPV. But among older females, the cost-effectiveness of Gardasil becomes less and less favorable

. . . .
 . . . [I]t cost about \$43,600 per “quality-adjusted life year” [(QALY)] gained[] when [the] HPV vaccine is administered to 12-year-old girls. This falls below the \$50,000 per quality-adjusted life year threshold that some researchers use as a maximum for cost-effectiveness. . . .

It would cost \$97,300 per QALY, however, to vaccinate girls and women through age 18, \$120,400 per QALY for girls and women up to age 21, and \$152,700 for girls and women up to age 26. The cost-effectiveness becomes more attractive when protection against genital warts is factored in.

Id.

¹⁸ See U.S. Food & Drug Admin., *supra* note 14. Gardasil is only *recommended* for use in girls and women between the ages of eleven and twenty-six. *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

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The Gardasil vaccine is administered through a series of three injections into a muscle in the upper arm or thigh.²⁴ The first shot may be given at any time if the female is between the ages of nine and twenty-six, with the second and third doses following within two and six months after the first shot.²⁵

A number of problems, medical or otherwise, have been reported as a result of the use of the Gardasil vaccine. The CDC reports that, as of September 1, 2009, forty-four deaths have been linked to the administration of Gardasil.²⁶ Further, as of September 1, 2009, the CDC and the FDA have received 15,037 Vaccine Adverse Event Reporting System (“VAERS”)²⁷ reports of adverse events or side effects following Gardasil vaccination in the United States.²⁸ “Of these reports, 93% were reports of events considered to be non-serious, and 7% were reports of events considered to be serious.”²⁹ Non-serious adverse events “included fainting, pain and swelling at the injection site (the arm), headache, nausea and fever.”³⁰ Serious adverse events included those involving “hospitalization, permanent disability, life-threatening illness, and death.”³¹ In particular, instances of blood clots and Guillain-Barré Syndrome (a rare disorder that causes muscle weakness)³² were reported and classified as serious adverse events.³³ Despite these reported events and deaths, the CDC and FDA “continue[] to recommend Gardasil vaccination for the prevention of 4 types of HPV.”³⁴

²⁴ Gardasil—Questions & Answers, <http://www.drugs.com/gardasil.html> (last visited July 9, 2009).

²⁵ *Id.*

²⁶ CDC—Reports of Health Concerns Following HPV Vaccination, <http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm> (last visited Oct. 27, 2009) [hereinafter “CDC Reports”].

²⁷ *Id.* According to the CDC, VAERS is “a useful early warning public health system that helps [the] CDC and FDA detect possible side effects or adverse events following vaccination.” *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² See Guillain-Barré Syndrome Fact Sheet: National Institute of Neurological Disorders and Stroke, http://www.ninds.nih.gov/disorders/gbs/detail_gbs.htm (last visited July 9, 2009). Guillain-Barré Syndrome is a disorder that causes the immune system to attack the peripheral nervous system. *Id.* (noting that the causes of this disorder are unknown). See generally Margaret J. Kochuba, Comment, *Public Health vs. Patient Rights: Reconciling Informed Consent with HPV Vaccination*, 58 EMORY L.J. 761, 761–62 (2009) (describing the case of a young woman who received the HPV vaccine and subsequently began to exhibit symptoms of Guillain-Barré, including tingling, numbness, muscle weakness, and, ultimately, paralysis).

³³ See CDC—Reports, *supra* note 26.

³⁴ *Id.*

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A number of medical professionals, scientists, and other commentators have attacked the approval of Gardasil because its use leads to a range of health problems in a not-insignificant percentage of its users. One noteworthy challenge concerns the fact that the FDA evaluated and approved Gardasil pursuant to a six-month-long priority review process, which the FDA utilizes “for products with potential to provide significant health benefits.”³⁵ Commentators argue that a period of six months is not long enough to show, with any degree of certainty, whether there is a correlation between the vaccine and the prevention of cervical cancer.³⁶

Additionally, a second argument is that a period of six months is not long enough to demonstrate whether use of the vaccine will cause health

³⁵ See U.S. Food & Drug Admin., *supra* note 14.

³⁶ See Lindsey R. Baden et al., *Human Papillomavirus Vaccine – Opportunity and Challenge*, 356 NEW ENG. J. MED. 1990, 1990 (2007) (suggesting that the efficacy of Gardasil is limited by two factors: (1) “not all cervical cancer is caused by HPV-16 or HPV-18;” and (2) it “appears necessary to vaccinate young women before they are infected with these two serotypes” because demonstrating a correlation between Gardasil and the prevention of cervical cancer “will require the long-term observation of a large number of treated women”); Charlotte J. Haug, *Human Papillomavirus Vaccination – Reasons for Caution*, 359 NEW ENG. J. MED. 861, 861 (2008).

[S]erious questions regarding the overall effectiveness of [Gardasil] in the protection against cervical cancer remain[] to be answered. . . . How can policymakers make rational choices about the introduction of medical interventions that might do good in the future, but for which evidence is insufficient, especially since we will not know for many years whether the intervention will work or—in the worst case—do harm?

Haug, *supra*, at 861; George F. Sawaya & Karen Smith-McCune, *HPV Vaccination – More Answers, More Questions*, 356 NEW ENG. J. MED. 1991, 1993 (2007).

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

Sawaya & Smith-McCune, *supra*, at 1993; Elisabeth Rosenthal, *Drug Makers’ Push Leads to Vaccines’ Fast Rise*, N.Y. TIMES, Aug. 20, 2008, at A1 (noting the high cost of the Gardasil vaccine, the comparatively short duration of the studies conducted on this vaccine, the connection between Merck, the manufacturer of Gardasil, and health providers and politicians, and the suggestion that a booster shot may be necessary to maintain the effectiveness of Gardasil in girls who receive the vaccine early in life); Laura Sparkes, *Gardasil Side-Effects Controversy*, Dec. 7, 2007, <http://au.todaytonight.yahoo.com/article/43654/health/gardasil-effects-controversy> (describing the side effects of Gardasil as evidenced in Australian women).

problems following the vaccination period or later in life.³⁷ Finally, commentators contend that the use of such an abbreviated review period, combined with the high price of Gardasil, suggests that Merck, Gardasil's manufacturer, requested and was granted a shorter consideration period in a bid for profits over safety.³⁸ This notion is supported by Merck's subsequent, aggressive campaign to get states to "pass laws requiring that preteen girls be vaccinated against cervical cancer in the face of a growing backlash among parents, physicians[,] and consumer advocates."³⁹

To a lesser extent, certain groups, particularly conservative religious groups such as the Family Research Council, criticize the approval of Gardasil, arguing that the use of the vaccine leads to sexual promiscuity among young women and encourages premarital sex.⁴⁰ Along with this critique has come the idea that mandatory Gardasil vaccination as a prerequisite for school entry⁴¹ infringes not only on individual rights, but

³⁷ See Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 387 (2008) ("[T]he adverse events reported since the vaccine's approval are, at the very least, a sobering reminder that rare adverse events may surface as the vaccine is administered to millions of girls and young women. Concerns have also been raised that other carcinogenic HPV types not contained in the vaccines will replace HPV types 16 and 18 in the pathological niche.").

³⁸ See Aaron Smith, *Merck Pitches Another Use for Gardasil*, CNN MONEY, Dec. 16, 2005, <http://money.cnn.com/2005/12/16/news/fortune500/merck/index.htm> (suggesting that Merck requested a fast-track review process of Gardasil from the FDA while the company faced "lawsuits, layoffs and the looming patent expiration of its top earner, Zocor").

³⁹ John Carreyrou & Sarah Rubenstein, *Merck Ends Lobbying for Cervical Cancer Vaccine*, WALL ST. J., Feb. 21, 2007, at A3 ("Merck's aggressive lobbying campaign was intended to boost sales of its Gardasil vaccine, which received [FDA] approval last year. . . . Merck [was] eager to build Gardasil's sales quickly to offset patent expirations on some of its best-selling drugs and its mounting legal costs over its withdrawn painkiller Vioxx.").

⁴⁰ See Giuseppe Aguanno, Note, *Cervical Cancer Prevention: Mandating the HPV Vaccine as a Condition of School Attendance*, 46 FAM. CT. REV. 637, 644 (2008) (noting that "social conservatives" have advanced the theory of "sexual disinhibition, the argument being that [Gardasil] will give youths a false sense of security and encourage them to engage in riskier sexual activity" but positing that "this argument is not empirically valid") (footnote omitted); Micah Globerson, *Protecting Women: A Feminist Legal Analysis of the HPV Vaccine, Gardasil*, 17 TEX. J. WOMEN & L. 67, 75-77 (2007) ("Conservatives, however, lament that widespread use of Gardasil represents implicit approval of premarital sex, undermining their pro-abstinence message."); see also Claire Dederer, *Pitching Protection, to Both Mothers and Daughters*, N.Y. TIMES, Feb. 18, 2007, http://www.nytimes.com/2007/02/18/arts/television/18dede.html?_r=1 ("[E]ven as Merck advertises directly to the consumer, it is lobbying state by state for a universal mandate that the vaccine be given to all girls. Pro-abstinence groups are leery of the mandate, as are groups that monitor the legislation of vaccines.").

⁴¹ Two Supreme Court cases are widely cited as justifying mandatory vaccination as a prerequisite to school entry. Julie E. Gendel, Comment, *Playing Games with Girls' Health: Why it is Too Soon to Mandate the HPV Vaccine for Pre-Teen Girls as a Prerequisite to School Entry*, 39 SETON HALL L. REV. 265, 276 (2009). The first is *Jacobson v. Massachusetts*, in which

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also on parental rights.⁴² Legal scholars also question whether mandatory HPV vaccination in the context of school attendance is constitutional because the state-sponsored mandates⁴³ are sex-specific and because they may violate the Due Process Clause.⁴⁴

the Supreme Court upheld a Massachusetts law allowing municipalities to require their residents, both adults and children, to be vaccinated against smallpox. 197 U.S. 11, 39 (1905). The second is *Zucht v. King*, in which the Court extended its holding in *Jacobson* to permit mandatory smallpox vaccination as a prerequisite to school attendance. 260 U.S. 174 (1922). Arguably, these cases should not be applied to support mandatory HPV vaccination of school-age girls and young women. “*Jacobson* and *Zucht* are still relevant in the modern context for diseases that are airborne and highly dangerous but should not be interpreted as permitting any and all vaccinations.” Gendel, *supra*, at 279 (footnote omitted); 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 because 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) (contending that HPV is “highly contagious,” thereby falling 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).

⁴² See R. Alta Charo, *Politics, Parents, and Prophylaxis – Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905, 1905 (2007) (“[T]he more important focus might be on the high cost of the vaccines—a cost that poses a genuine obstacle to patients, physicians, and insurers—concern has focused instead on a purported interference in family life and sexual mores.”). While the introduction of Gardasil as a mandatory vaccination that is a necessary prerequisite for school entry is outside the scope of this article, a number of commentators question whether the states’ adoption of mandates espousing this requirement is constitutional or otherwise appropriate. Compare Aguanno, *supra* note 40, at 648 (“States, with the financial support of the federal government, should pass legislation mandating that all females entering the sixth grade be vaccinated with the HPV vaccine. Such legislation does not violate parents’ constitutional right to decide health issues for their children.”), with Deana Pollard Sacks, *Elements of Liberty*, 61 SMU L. REV. 1557, 1599–1603 (2008). Suggesting that:

[i]f a mandatory HPV vaccine law is passed, it will likely be challenged as a violation of substantive due process.

....

... It seems unlikely that a state could meet its burden of showing that the vaccine is necessary if the HPV strains at issue are entirely avoidable through personal choices such as sexual abstinence or very careful sexual practices, considering the potential health risks of vaccine and the nature of its impact on individual liberty. However, if the state includes an opt-out provision, the preservation of individual autonomy may sufficiently protect personal autonomy to render the law constitutional.

Id. (footnotes omitted).

⁴³ To date, at least forty-one states and the District of Columbia “have introduced legislation to require, fund or educate the public about the HPV Vaccine.” HPV Vaccine: State Legislation, <http://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited Oct. 27, 2009). Indiana has enacted legislation requiring parents to receive information about the vaccine and to tell schools whether or not they have vaccinated their children against HPV but not mandating the vaccine itself for school attendance. *Id.* Iowa, Nevada,

Finally, as previously mentioned, Gardasil is criticized because of its high cost, which makes it more expensive than most other vaccines and more difficult to obtain, particularly by low and middle class girls and women in the United States (this criticism is specifically directed at Merck's pricing structure). According to the CDC, the retail price of the Gardasil vaccine is approximately \$125 per shot, or \$375 for the full series of inoculations.⁴⁵ Not only does this price make Gardasil too expensive for many girls and women living in the United States, but it also makes the vaccine prohibitively costly for females living outside the United States and specifically in developing countries, where the vaccine is arguably most needed.

According to Professor Kevin Outterson:

New Mexico, and Rhode Island have signed into law legislation requiring insurance companies to cover HPV vaccinations. *Id.* Louisiana, Michigan, North Carolina, North Dakota, Texas, and Washington have enacted legislation requiring schools to provide HPV information and vaccines under certain circumstances. *Id.* Maine has enacted a law establishing financial coverage for the HPV vaccine through the Maine Care program and improving public awareness of the vaccine. *Id.* Maryland has passed a law establishing a task force for the HPV vaccine that makes recommendations for a state plan for the vaccine. *Id.* Minnesota has passed a law reconvening the cervical cancer elimination study concerning the risks, benefits, availability, efficacy, and coverage of the HPV vaccine. *Id.* New Mexico has enacted legislation creating an HPV advisory panel to study cervical cancer disparities and find cost-effective strategies for primary and secondary cervical cancer interventions, including the HPV vaccine. *Id.* New York has enacted a budget bill that allocates five million dollars to promote the HPV vaccine. *Id.* Utah has adopted a law establishing an awareness campaign on the causes, prevention, and risks of cervical cancer. *Id.* Several states, including New Hampshire and South Dakota, have announced that they will provide the Gardasil vaccine to girls under the age of eighteen at no cost. *Id.* Further, in 2007, "at least 24 states and [the District of Columbia] introduced legislation to specifically mandate the HPV vaccine for school." *Id.*

Effective October 1, 2008, Virginia requires the HPV vaccine for girls entering the sixth grade (on or after their eleventh birthday) although it allows parents to exempt their child. *Id.* A similar bill has been enacted in the District of Columbia, but its start date has been pushed back until the fall of 2009. *Id.* Thus, Virginia is the only state that currently requires girls and young women to receive the Gardasil vaccine as a condition of school attendance.

⁴⁴ See Javitt et al., *supra* note 37, at 392 ("A sex-based mandate for HPV vaccination could be challenged on two grounds: first, under the Equal Protection Clause because it distinguishes based on gender and second, under the Due Process Clause, because it violates a protected interest in refusing medical treatment.").

⁴⁵ See HPV Vaccine Information for Young Women, <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-young-women.htm> (last visited July 9, 2009). This price can be as high as \$400 to \$500, however, after doctors' fees are factored in. See Rob Stein, *Vaccine for Girls Raises Thorny Issues*, WASH. POST, Nov. 7, 2006, at HE1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/11/03/AR2006110301966.html>.

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[i]n high-income countries, deaths from cervical cancer are relatively rare due to expensive population screening and treatment. About 260,000 women in developing countries die from cervical cancer each year, exceeding the deaths from all diseases in the tropical-disease cluster.⁴⁶

....

[T]he price... [of Gardasil] exceeds the per capita annual health budgets for most of the women worldwide who need it.⁴⁷

....

Merck has announced an equitable access program⁴⁸ and some limited donations,⁴⁹ but the scope of the program remains unknown at the present.⁵⁰

⁴⁶ Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities be Limited to Specific Diseases?*, 34 AM. J.L. & MED. 279, 292 (2008).

⁴⁷ *Id.*

⁴⁸ See Gardasil Program Overview, <http://www.gardasil-access-program.com/section/141> (last visited July 9, 2009).

The [Gardasil] Access Program plans to make available at least 3 million doses of [Gardasil] . . . for use in projects in eligible low income countries throughout the world.

. . . The [Gardasil] Access Program [(the "Program")] strives to overcome the challenges to achieving vaccine access in developing world nations and empowers resource-poor nations and their partners to develop programs to bring this vaccine to people in need.

. . . [The Program] does not aim to cover nationwide HPV vaccine programs. [It] will draw upon the learnings [sic] and experiences from participating organizations and seek to contribute to knowledge on how to successfully implement HPV vaccine access programs in developing countries.

The . . . Program, which is planned to run over a 5-year period, is made possible by a pledge from Merck & Co Inc., . . . and is overseen by Axios Healthcare Development (AHD), a US non-profit company. AHD administers the donation program, reviews and approves applications, and ensures prompt delivery of the vaccine to the recipients, with the technical assistance of Axios International, a public health consultancy specializing in developing and emerging countries.

Id.

To qualify for receipt of Gardasil through the Access Program, organizations and institutions in eligible low-income countries must apply to the Access Program and independent experts will review their applications using the following criteria: (1) demonstration of government approval (letter from the ministry of health); (2) quality of the programmatic approach or program design, including the applicant's "vaccine delivery

....

The deaths of less than 17,000 women per year in wealthy countries offered sufficient financial rewards to prompt both Merck and GlaxoSmithKline⁵¹ to spend hundreds of millions of dollars to bring HPV vaccines to market. . . . [The] deaths of more than 222,000 poor women per year may [not provide the necessary financial rewards to these companies,] . . . moral, scientific or humanitarian incentives to create HPV vaccines, . . . since these women cannot afford [vaccines like Gardasil].”⁵²

III. THE GARDASIL VACCINE AS A NATURALIZATION PREREQUISITE

Effective as of July 1, 2008, the CDC revised its vaccination requirements to mandate the Gardasil vaccine as a predicate for any female seeking either admission to the United States as an immigrant or a visa status readjustment to that of permanent resident.⁵³ This revision

experience, planned human resources, transportation and supply chain management[,] . . . program coordination[, and p]lanned communication about the vaccine program to targeted communities”; (3) quality of the protocol regarding the customs clearance and storage of the vaccine; (4) the soundness of the monitoring and evaluation process, including “how the [organization or] institution will identify and describe challenges, opportunities, and learnings in program implementation”; and (5) the level of the quality assurance process, particularly “how the program will ensure that all people who received the first dose will receive the remaining two doses of the vaccine at the right time.” See Gardasil Eligibility Criteria, <http://www.gardasil-access-program.com/section/143> (last visited July 9, 2009).

⁴⁹ Outterson, *supra* note 46, at 292–93.

⁵⁰ *Id.* at 293.

⁵¹ See *supra* note 15 and accompanying text (introducing GlaxoSmithKline and its version of the HPV vaccine – Cervarix).

⁵² Outterson, *supra* note 46, at 293.

⁵³ Memorandum from Dep’t of Health & Human Servs., Div. of Global Migration & Quarantine to Civil Surgeons 1, May 8, 2008, http://www.cdc.gov/ncidod/dq/pdf/civil_surgeon_ti/memo_.pdf. See also Questions & Answers: Changes to the Tuberculosis and Vaccination Requirements Required for Adjustment of Status, <http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnnextoid=1758d5b07655b110VgnVCM1000004718190aRCRD&vgnnextchannel=da3eaca797e63110VgnVCM1000004718190aRCRD> (last visited July 9, 2009) (noting that the CDC, after revising its vaccination requirements, now requires the following additional vaccinations in order to adjust status to legal permanent resident: (1) Rotavirus; (2) Hepatitis A; (3) Meningococcal; (4) Human papillomavirus; and (5) Zoster). Although these requirements became effective on July 1, 2008, the “CDC approved a 30 day grace period until August 1, 2008. Therefore, for any medical exam conducted on or after August 1, 2008, the new vaccinations, if appropriate, must be administered in order for USCIS to approve the applicant for adjustment of status.” *Id.*

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followed the announcement of the United States Advisory Committee for Immunization Practices (“ACIP”) that females aged eleven to twenty-six were to be routinely vaccinated against HPV.⁵⁴ Although the immunization recommendations issued by ACIP are advisory with respect to individuals who are United States citizens, Section 212 of the Illegal Immigration Reform and Responsibility Act of 1996 (the “Act”) requires individuals seeking permanent residency in the United States to get all of the vaccinations recommended by ACIP and to provide documentation of the vaccinations.⁵⁵

Specifically, the Act states that an alien is ineligible for admission to the United States or for an adjustment of her immigration status to that of lawful permanent resident if she fails “to present documentation of having received vaccination against vaccine-preventable diseases, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, influenza type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee for Immunization Practices.”⁵⁶

Nevertheless, these requirements can be waived under certain, narrowly described circumstances. According to the Act, the Attorney General may waive the Act’s requirement that an alien present documentation proving her receipt of mandatory inoculations in the case of any alien:

(A) who receives vaccination against the vaccine-preventable disease or diseases for which the alien has

⁵⁴ Lauri E. Markowitz et al., *Quadrivalent Human Papillomavirus Vaccine: Recommendation of the Advisory Committee on Immunization Practices (ACIP)*, March 23, 2007, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm?s_cid=rr5602a1_e.

⁵⁵ See 8 U.S.C. § 1182(a)(1)(A)(ii) (2006); see also Rosemary Black, *New Gardasil Cervical Cancer Vaccination Requirement for Immigrants Stirs Controversy*, DAILY NEWS (N.Y.), Oct. 24, 2008, http://www.nydailynews.com/lifestyle/health/2008/10/24/2008-10-24_new_gardasil_cervical_cancer_vaccination-1.html (“Now, immigrants will be required to receive a vaccine that’s not even required in this country ‘Through an interesting quirk, now all these immigrant girls and young women will be protected against cancer. Immigrants will be better protected against cancer than our own population.’”); Mary Engel, *Immigrants’ Advocates Decry Cervical Cancer Vaccine Order*, L.A. TIMES, Oct. 22, 2008, <http://articles.latimes.com/2008/oct/22/science/sci-gardasil22> (“Unknown to many immigrant and health advocates, a 1996 immigration law directs the Citizenship and Immigration Services to require that new immigrants receive inoculations that the CDC’s immunization committee recommends for U.S. residents. ‘It’s not really a decision of ours,’ said [an] immigration service spokeswoman”); Anabelle Garay, *Vaccine Requirement Called Unfair*, DENVER POST, Oct. 3, 2008, http://www.denverpost.com/search/ci_10622872 (“A 1996 change to the nation’s immigration laws requires anyone seeking permanent residency to get all the vaccinations recommended by the [C]ommittee.”).

⁵⁶ 8 U.S.C. § 1182(a)(1)(A)(ii) (emphasis added).

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failed to present documentation of previous vaccination, (B) for whom a civil surgeon, medical officer, or panel physician . . . certifies, according to such regulations as the Secretary of Health and Human Services may prescribe, that such vaccination would not be medically appropriate,⁵⁷ or (C) under such circumstances as the Attorney General provides by regulation, with respect to whom the requirements of such a vaccination would be contrary to the alien's religious beliefs or moral convictions^{58, 59}

Further, the Attorney General may waive the application of the Act's vaccination requirement "in the case of any alien, in accordance with such terms, conditions, and controls, if any, including the giving of bond, as the Attorney General, in the discretion of the Attorney General after consultation with the Secretary of Health and Human Services, may by regulation prescribe."⁶⁰

Despite the existence of these waiver grounds, they are still quite limited, most requiring the approval of the Attorney General. Further, to qualify for a vaccine waiver, an alien must complete Form I-601 entitled

⁵⁷ The CDC has determined that a vaccination is not medically appropriate in the following five scenarios:

[1] the vaccine is not recommended by the ACIP for the alien's specific age group; [(2)] the vaccine is medically contraindicated (e.g., allergies to eggs or yeast, hypersensitivity to prior vaccines, and pregnancy, among other medical reasons); [(3)] the alien has taken the initial vaccines, but is unable to complete the entire series within a reasonable period of time (e.g., the recommended series of hepatitis vaccines may take as long as 6 months to complete); [(4)] the medical examination is not being performed during the fall (flu) season; [and (5) in the case of] immigrant visa applicants abroad, [if] . . . the vaccination is not available.

Memorandum from Johnny N. Williams, Executive Assoc. Comm'r, Office of Field Operations, U.S. Dep't of Justice Immigration and Naturalization Serv., to the Reg'l Dir. & Deputy Executive Assoc. Comm'r of the Immigration Servs. Div. & to the Dir. of the Office of Int'l Affairs, Medical Examinations, Vaccination Requirements, Waivers of Medical Grounds of Inadmissibility, and Designation of Civil Surgeons and Revocation of Such Designation 31 (Oct. 17, 2002), <http://www.immigrationequality.org/uploadedfiles/2002%20HIV%20Immigration%20policy%20memo.pdf>.

⁵⁸ To obtain a waiver of the vaccination requirements based on the fact that a certain vaccination is contrary to her religious beliefs or moral convictions, an alien must prove that (1) she is opposed to vaccinations in any form; (2) the objection is based on religious beliefs or moral convictions, not mere preferences; and (3) the religious or moral beliefs must be sincere. *See id.* at 36-37.

⁵⁹ 8 U.S.C. § 1182(g)(2) (2006).

⁶⁰ *Id.* § 1182(g)(3).

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“Application for Waiver of Ground of Inadmissibility”⁶¹ and submit this form to either the local American Embassy or Consulate (if the alien is not currently in the United States) or to the local U.S. Citizenship and Immigration Services Office having jurisdiction over the alien’s place of residence.⁶² The fee for submitting this form is \$545, which is not waived unless the alien “has tuberculosis, is mentally retarded, or has a history of mental illness.”⁶³ Thus, the cost of the waiver application is nearly \$200 greater than the cost of the full course (or three shots) of the Gardasil vaccine, which makes it unlikely that an immigrant would attempt to opt out of the vaccine, even if she knew about the Act’s waiver provision and satisfied one of the provision’s narrow requirements.

IV. OPPOSITION TO GARDASIL AS A NATURALIZATION PREREQUISITE

Putting forth social, economic, and cultural arguments, a number of organizations and commentators object to the fact that immigrant girls and women must be vaccinated against HPV prior to obtaining United States citizenship, whereas the vaccine is only recommended for current United States citizens. As was previously noted, the high cost of the Gardasil vaccine is much more likely to adversely affect non-citizen immigrants, as opposed to U.S. citizens.⁶⁴ Not only is the cost of Gardasil prohibitive for immigrant women (in fact, the cost of Gardasil is prohibitive for many American women), but this expense is compounded by the many other fees associated with the naturalization process that immigrant women must pay in order for their naturalization application to be processed and adjudicated.⁶⁵

Moreover, commentators argue that the imposition of the Gardasil mandate on immigrant women treats these women as clinical test

⁶¹ See USCIS—Immigration Forms, <http://www.uscis.gov/portal/site/uscis/menuitem.eb1d4c2a3e5b9ac89243c6a7543f6d1a/?vgnextoid=db029c7755cb9010VgnVCM1000045f3d6a1RCRD&vgnnextchannel=db029c7755cb9010VgnVCM10000045f3d6a1RCRD> (last visited July 9, 2009).

⁶² See USCIS—Application for Waiver of Ground of Inadmissibility, <http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnextoid=bb515f56ff55d010VgnVCM10000048f3d6a1RCRD&vgnnextchannel=db029c7755cb9010VgnVCM10000045f3d6a1RCRD> (last visited July 9, 2009).

⁶³ *Id.*

⁶⁴ See *supra* notes 45–52 and accompanying text.

⁶⁵ See *HPV Vaccine Mandated for Green Card Applicants*, USA TODAY, Oct. 2, 2008, http://www.usatoday.com/news/health/2008-10-02-hpv-green-card_N.htm [hereinafter “HPV Vaccine Mandated”] (“At a cost of \$400, Gardasil places an added burden on green card applicants already paying more than \$1,000 in form fees and hundreds of dollars for mandatory medical exams, advocates say.”).

subjects.⁶⁶ In effect, it prevents female immigrants from making an informed choice about whether or not they would like to receive a potentially dangerous vaccine whose side effects and long-term effects are not yet fully understood. While requiring the Gardasil vaccine for immigrant women may present scientists studying the effects of the vaccine with a perfect set of clinical test subjects, non-immigrant females who are United States citizens and who have no obligation to receive the vaccine benefit by avoiding any potential harms that may result from the administration of Gardasil.

Closely tied to the notion of immigrant women as clinical test subjects is the idea that the Gardasil vaccine requirement does not address the disproportional impact that “cervical cancer has . . . on certain immigrants, particularly Latinas and certain ethnic Asian groups including Vietnamese, Korean and Hmong women.”⁶⁷ Because young immigrant women often cannot afford to pay for medical care and health insurance they frequently have “difficulty . . . finding culturally competent services . . . [and] must often forego routine preventative health care services such as pap smears. These inequalities in access contribute to [young immigrant women’s] high rates of cervical

⁶⁶ See Press Release, Nat’l Coal. for Immigrant Women’s Rights Statement: HPV Vaccination Requirement Discriminates Against Immigrant Women, Sept. 29, 2008, <http://www.now.org/issues/diverse/nciwr/100108immigrationhpv.html>. In its statement on the issue, the National Coalition for Immigrant Women’s Rights (“NCIWR”) declared that the United States:

has a longstanding history of using immigrants as test subjects. This current policy, at best, sends the unfair message that only U.S. citizen women have the right to weigh the risks associated with Gardasil while immigrant women do not. At worst, the new rule is a continuation of an ugly history of using immigrant women as involuntary clinical trial subjects.

Id. In urging U.S. Citizenship and Immigration Services (“USCIS”) to remove the HPV vaccination requirement, NCIWR notes that:

[i]f the true intent of USCIS is to look out for the health of immigrant girls and young women, then there are far more just ways of going about it. . . . [T]he logical solution is for USCIS to work with the Department of Health and Human Services to make pap smears more accessible and affordable to immigrant girls and women since that is the most effective way to detect abnormal cell growth that could lead to cervical cancer.

Id. See also Susan Donaldson James, *Girl Rejects Gardasil, Loses Path to Citizenship*, ABC News, Sept. 11, 2009, <http://abcnews.go.com/Health/ReproductiveHealth/gardasil-vaccine-roadblock-citizenship/story?id=8542051> (describing the story of a 17-year-old British woman who is facing “removal” from the United States because she refuses to receive the Gardasil vaccine for religious reasons and because she is concerned about this vaccine’s safety).

⁶⁷ *Id.*

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cancer.”⁶⁸ The Gardasil requirement only exacerbates these problems, instead of solving them.

Finally, and perhaps most importantly, many argue that the Gardasil vaccine became a prerequisite to naturalization purely by accident—that the CDC did not intend to condition permanent residency status of young immigrant girls and women on their receipt of the Gardasil vaccine.⁶⁹ “Jon Abramson, who chaired the CDC’s Advisory Committee on Immunization Practices, said the panel never intended to require Gardasil for immigrants and wasn’t aware its recommendation would become mandatory.”⁷⁰ Moreover, even Merck, Gardasil’s manufacturer that lobbied extensively for FDA approval of Gardasil and for state laws mandating HPV vaccination as a prerequisite for school enrollment and attendance, did not intend for the Gardasil vaccine to be a bar to permanent residency status and naturalization for female immigrants. In fact, a Merck spokeswoman “said the drug company did not lobby the government to require the vaccine for female immigrants and that it wasn’t aware of the mandate until after the rule took effect.”⁷¹

As a result, more than 100 organizations and other groups representing immigrants’ rights, women’s rights, public health, medicine, and reproductive justice, including the American College of Obstetricians and Gynecologists (“ACOG”), the American Immigration Lawyers Association, and the Planned Parenthood Federation of America,⁷² urge the CDC to remove Gardasil “from the list of required vaccinations for female immigrants seeking permanent residence or entry to the US . . . [and to] direct the US Office of Citizenship and Immigration Services to suspend the HPV vaccination requirement for immigrants seeking to adjust their immigration status or to obtain visas to the US.”⁷³

⁶⁸ *Id.*

⁶⁹ See *HPV Vaccine Mandated*, *supra* note 65.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Letter from Nat’l, State & Int’l Orgs. to Dr. Richard Besser, Acting Dir., Ctrs. for Disease Control & Prevention, Jan. 26, 2009, <http://napawf.org/blog/?p=47>.

⁷³ Likely prompted by this outcry against the Gardasil vaccine requirement, the CDC had proposed, in April 2008, the following criteria to determine which vaccinations recommended by the ACIP for the general population (in addition to those vaccines specifically mentioned in Section 212 of the Immigration and Nationality Act) will be required for immigrants seeking entry into the United States or an adjustment of their status to that of lawful permanent resident: “(1) The vaccine must be an age-appropriate vaccine as recommended by [the] ACIP for the general U.S. population, and (2) At least one of the following: (a) The vaccine must protect against a disease that has the potential to cause an outbreak, (b) the vaccine must protect against a disease that has been eliminated in the United States, or is in the process for elimination in the United States.” Criteria for

V. CONSTITUTIONAL ISSUES CONCERNING GARDASIL AS A NATURALIZATION PREREQUISITE

Although social, economic, and cultural arguments support the overturning of the Gardasil vaccination requirement for female immigrants who seek to enter the United States, change their residency status, and eventually become United States citizens, the requirement also presents significant constitutional concerns. For example, because the Gardasil mandate only pertains to women and affects individuals who are not United States citizens, it potentially violates the Due Process Clauses of the Fifth and Fourteenth Amendments and goes against the concept of equal protection that is enshrined in the Fifth and Fourteenth Amendments.⁷⁴

Further, the Gardasil vaccination requirement results in the use of female immigrants as test subjects for a vaccine whose long-term effects have not been studied, has a range of side effects, and causes death in

Vaccination Requirements for U.S. Immigration Purposes, 74 Fed. Reg. 15, 986 (April 8, 2009).

In November 2009, the CDC stated that it had adopted these criteria, noting in the explanatory comments that the guidelines would not apply to the HPV vaccine and that, as a result, the HPV vaccine would not be mandatory for immigrant women who wish to become permanent residents or to change their residency status as of December 14, 2009. See *Criteria for Vaccination Requirements for U.S. Immigration Purposes*, 74 Fed. Reg. 58,636 (Nov. 13, 2009). Despite this unequivocal language, these new guidelines do not and cannot change the language or the applicability of the Act, which unquestionably states that any vaccine recommended by ACIP becomes mandatory for immigrants to the United States, 8 U.S.C. 1182(a)(1)(A)(ii)), because the “CDC has no direct regulatory power. It provides epidemiologic information and technical support to other regulatory agencies and information to medical providers and the public, but relies on the FDA and other Public Health Service agencies to implement its recommendations.” Sherry Glied, *Markets Matter: U.S. Responses to the HIV-Infected Blood Tragedy*, 82 Va. L. Rev. 1493, 1495-96 (1996). Indeed, the CDC’s recommendations have frequently been ignored, particularly “in the face of opposition from powerful interest groups.” *Id.* at 1496. Moreover, as the CDC itself pointed out in the comments to the newly adopted guidelines, it has no authority or control over either ACIP or the U.S. Citizenship and Immigrations Services agency. See *Criteria for Vaccination Requirements for U.S. Immigration Purposes*, 74 Fed. Reg. 58,637 (Nov. 13, 2009). In effect, the CDC is currently attempting to amend the text of an Act of Congress without the benefit of bicameral consideration, debate, and vote—an impermissible result. See Randolph J. May, *Defining Deference Down: Independent Agencies and Chevron Deference*, 58 Admin. L. Rev. 429, 433 n. 21 (2006) (citing *Natural Res. Def. Council, Inc. v. Gorsuch*, 685 F.2d 718, 720 (D.C. Cir. 1982)) (stating that a change in the interpretation of a word in an Act of Congress adopted by the EPA—an agency with actual regulatory powers—was impermissible because the new interpretation would contradict Congress’s intent). The only way in which the Gardasil vaccine requirement can be changed is through the revocation of ACIP’s recommendation of the vaccine or through the amendment of the Act by Congress itself.

⁷⁴ See *supra* note 44 and accompanying text.

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some women. As a result, the requirement could violate the due process guarantees encapsulated in the Fifth and Fourteenth Amendments.

Therefore, suspending this requirement eliminates not only the broader concerns surrounding the Gardasil vaccine mandate, but also eradicates the constitutional problems this requirement raises. This Part of the Article first describes the background of the Fourteenth Amendment as it relates to non-citizens and then argues that the Gardasil vaccination mandate potentially violates the Fifth and Fourteenth Amendments.

A. *The Fourteenth Amendment as Applied to Non-Citizen Resident Aliens, Generally*

Many scholars generally argue that the Constitution, by its terms, is a universal text, meaning that “the liberties enumerated in the Bill of Rights and elsewhere are afforded generally to ‘persons’ or ‘the people.’”⁷⁵ According to Sarah Cleveland, “most of the Constitution’s provisions are not textually restricted by either the population or the geographic area to which they apply. Instead, they define the general powers of the national government or impose general limits on the exercise of these powers.”⁷⁶

Specific constitutional provisions illustrate this point. “[F]or example, Article I [of the Constitution] unqualifiedly prohibits the suspension of habeas corpus and the adoption of *ex post facto* laws or bills of attainder.”⁷⁷ Moreover, the Constitution seems to distinguish between rights held by the “people” and those held by “persons,” which suggests that certain constitutional rights are reserved for all persons—citizens and non-citizens—while others are retained only by United States citizens.⁷⁸ The First (the right to peaceably assemble), Second, Fourth, Ninth, Tenth, and Seventeenth Amendments refer to the “people,”⁷⁹ while the Fourth, Fifth, and Fourteenth Amendments refer to

⁷⁵ Timothy Zick, *Constitutional Displacement*, 86 WASH. U. L. REV. 515, 531 (2009) (citing U.S. CONST. art. I, § 9; U.S. CONST. amends. V, X, XIV).

⁷⁶ Sarah H. Cleveland, *Powers Inherent in Sovereignty: Indians, Aliens, Territories, and the Nineteenth Century Origins of Plenary Power Over Foreign Affairs*, 81 TEX. L. REV. 1, 19 (2002).

⁷⁷ Zick, *supra* note 75, at 531 (emphasis added) (citing U.S. CONST. art. I, § 9).

⁷⁸ Since Article 1, Section 2 of the Constitution specifies not only that representatives are chosen by the people of the several states, but also that apportionment is determined by the number of persons among the several states (including the three-fifths rule), it seems that the term “people” refers to citizens, and the term “persons” refers to both citizens and non-citizens. See U.S. CONST. art. I, § 2.

⁷⁹ See U.S. CONST. amends. I, II, IV, IX, X, XVII.

“persons.”⁸⁰ The other Amendments are neutral on the terminology, or use the term “citizens.” Only the Twenty-Second Amendment uses the term “person” in a way that excludes non-citizens.⁸¹ Thus, logically, the rights accorded to the “people” should be reserved for citizens and those assigned to “persons” (including rights not specified, such as Eighth Amendment rights) should be accorded to all.

The Framers’ understanding of the Constitution, particularly that of James Madison, seems to be largely consistent with scholars’ understanding of the Constitution, as well as with the argument concerning the text of the Constitution, itself.⁸² In his *Report on the Virginia Resolutions*, which criticized the Alien and Sedition Acts of 1798, James Madison stated:

Again, it is said that, aliens not being parties to the Constitution, the rights and privileges which it secures cannot be at all claimed by them.

To this reasoning, also, it might be answered that, although aliens are not parties to the Constitution, it does not follow that the Constitution has vested in Congress an absolute power over them. The parties to the Constitution may have granted, or retained, or modified, the power over aliens, without regard to that particular consideration.

⁸⁰ See *United States v. Verdugo-Urquidez*, 494 U.S. 259, 265–66 (1990); see also U.S. CONST. amends. IV, V, XIV.

⁸¹ See U.S. CONST. amend. XXII.

No person shall be elected to the office of the President more than twice, and no person who has held the office of President, or acted as President, for more than two years of a term to which some other person was elected President shall be elected to the office of the President more than once.”). Article II, Section 1, Clause 4 of the Constitution specifically defines the term “President” to mean “a natural born Citizen, or a Citizen of the United States, at the time of the Adoption of this Constitution

U.S. CONST. art. II, § 1, cl. 4. As a result, the term “person,” as it is used in the Twenty-Second Amendment, refers only to United States citizens. U.S. CONST. amend. XXII.

⁸² Some scholars argue that the Framers took care to make it clear that rights recognized in the Constitution were those of persons, not of citizens. See Jon Roland, *The Social Contract and Constitutional Republics* (1994), <http://www.constitution.org/soc/cont.htm> (“Yet constitutions recognize the power to deprive persons of their rights under *due process* of law. Strictly speaking, a person may not be deprived of such rights in the sense of taking them away. Natural rights are never lost.”).

But a more direct reply is, that it does not follow, because aliens are not parties to the Constitution, as citizens are parties to it, that, whilst they actually conform to it, they have no right to its protection. Aliens are not more parties to the laws than they are parties to the Constitution; yet it will not be disputed that, as they owe, on one hand, a temporary obedience, they are entitled, in return, to their protection and advantage.

If aliens had no rights under the Constitution, they might not only be banished, but even capitally punished, without a jury or the other incidents to a fair trial. But so far has a contrary principle been carried, in every part of the United States, that, except on charges of treason, an alien has, besides all the common privileges, the special one of being tried by a jury, of which one half may be also aliens.⁸³

Similarly, Alexander Hamilton defended the broad notion of according aliens the same rights as United States citizens. In *The Works of Alexander Hamilton*, Hamilton stated:

The right to seize and confiscate individual property, in national wars, excludes all those cases where the individual derives his title from the enemy sovereign or nation: for the right to property always implies the right to be protected and secured in the enjoyment of that property; and a nation, by the very act of permitting the citizen of a foreign country to acquire property within its territory, whether to lands, funds, or to any other thing, tacitly engages to give protection and security to that property, and to allow him as full enjoyment of it as any other proprietor—an engagement which no state of things between the two nations can justly or reasonably affect. Though politically right, that, in wars between nations, the property of private persons, which depend

⁸³ JAMES MADISON, MADISON'S REPORT ON THE VIRGINIA RESOLUTIONS (1799-1800), reprinted in 4 THE DEBATES IN THE SEVERAL STATE CONVENTIONS OF THE ADOPTION OF THE FEDERAL CONSTITUTION (Jonathan Elliot, ed., 2d ed., 1827), available at http://oll.libertyfund.org/?option=com_staticxt&staticfile=show.php%3Ftitle=1908&chapter=112456&layout=html&Itemid=27; see also 11 THOMAS JEFFERSON, THE WRITINGS OF THOMAS JEFFERSON 341 (Albert Ellery Bergh, ed., Thomas Jefferson Memorial Association 1905) (1853) ("[A]n equal application of law to every condition of man is fundamental.").

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on the laws of their own country, or on circumstances foreign to the nation with which their own is at war, should be subject to seizure and confiscation by the enemy nation; yet it is both politically and morally wrong, that this should extend to property acquired under the faith of the [G]overnment, and the laws of that enemy nation.

When the [G]overnment enters into a contract with the citizen of a foreign country, it considers him as an individual in a state of nature, and contracts with him as such. It does not contract with him as the member of another society.⁸⁴

Since 1886, the Supreme Court of the United States has extended various constitutional rights, including Fourteenth Amendment protections, to resident aliens (both illegal aliens and non-citizen permanent residents or legal aliens) living in the United States.⁸⁵ In *Plyler v. Doe*, the Court held that illegal aliens were entitled to equal protection of the law under the Equal Protection Clause of the Fourteenth Amendment.⁸⁶ In reaching this decision, the Court examined the text of the Fourteenth Amendment and noted that it:

⁸⁴ 3 ALEXANDER HAMILTON, THE WORKS OF ALEXANDER HAMILTON 291-92 (Henry Cabot Lodge, ed., Fed. ed., G.P. Putnam's Sons 1904).

⁸⁵ See *Johnson v. Eisentrager*, 339 U.S. 763, 770-71 (1950). Aliens, even aliens whose presence in the United States is unlawful, have long been recognized as "persons" who are guaranteed due process of law by the Fifth and Fourteenth Amendments. See *Kwong Hai Chew v. Colding*, 344 U.S. 590, 596 (1953); *Shaughnessy v. Mezei*, 345 U.S. 206, 212 (1953); *Wong Wing v. United States*, 163 U.S. 228, 238 (1896); *Yick Wo v. Hopkins*, 118 U.S. 356, 369 (1886). Indeed, the Supreme Court has clearly held that the Fifth Amendment protects aliens whose presence in the United States is unlawful from invidious discrimination by the federal government. See *Mathews v. Diaz*, 426 U.S. 67, 77 (1976) ("[I]t would be incongruous to hold that the United States, to which the Constitution assigns a broad authority over both naturalization and foreign affairs, is barred from invidious discrimination with respect to unlawful aliens, while exempting the States from a similar limitation."); *Plyler v. Doe*, 457 U.S. 202, 210 n.9 (1982). See also *Mathews*, 426 U.S. at 84-86.

⁸⁶ See HIROSHI MOTOMURA, AMERICANS IN WAITING: THE LOST STORY OF IMMIGRATION AND CITIZENSHIP IN THE UNITED STATES 77-78 (2006) ("*Plyler* extended constitutional protections to the undocumented not based on immigration as contract or affiliation, but rather on presence on U.S. territory."); Hiroshi Motomura, *Immigration Outside the Law*, 108 COLUM. L. REV. 2037, 2043 (2008) (construing *Plyler* to stand for the proposition that the Constitution protects non-citizens as persons even if they are in the United States unlawfully); Linda Bosniak, *Persons and Citizens in Constitutional Thought* 6 (Feb. 11, 2008) (unpublished manuscript prepared for Harvard Public Law Conference on Religion, Multiculturalism, and Citizenship, Feb. 29-Mar. 1, 2008, on file with the Columbia Law Review) (suggesting that it would be "almost unthinkable" for the current Supreme Court to undo *Plyler's* recognition of "undocumented immigrants as constitutional persons").

is not confined to the protection of citizens. It says: "Nor shall any state deprive any *person* of life, liberty, or property without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." *These provisions are universal in their application, to all persons within the territorial jurisdiction, without regard to any differences of race, of color, or of nationality; and the protection of the laws is a pledge of the protection of equal laws.*⁸⁷

The Court further explained that the legislative history of the Fourteenth Amendment confirmed the notion that it "sought expressly to ensure that the equal protection of the laws was provided to the alien population."⁸⁸

According to the Supreme Court, the Due Process Clause of the Fourteenth Amendment also applies to persons regardless of whether their presence within the United States "is lawful, unlawful, temporary, or permanent."⁸⁹ The Court has even held that the Due Process Clause protects an alien subject to a final order of deportation,⁹⁰ though the nature of this protection varies depending upon the status of the alien and the circumstances surrounding the deportation.⁹¹

In *Wong Wing v. United States*, the Court determined that a statute imposing a punishment of a year of hard labor upon aliens subject to a final deportation order was unconstitutional.⁹² Specifically, the Court held that punitive measures could not be imposed upon aliens who were ordered to be removed from the United States because "all persons

⁸⁷ *Plyler*, 457 U.S. at 212 (first emphasis added) (citing *Yick Wo*, 118 U.S. at 369). See also *supra* note 85 and accompanying text.

⁸⁸ *Plyler*, 457 U.S. at 214. For example, Representative Bingham, in commenting on the Civil Rights Bill of 1866, repeatedly referred to the need to provide protection not only to the freedmen, but also to "the alien and stranger" and to "refugees . . . and all men." *Id.* at 214 n.13 (citations omitted). Senator Howard was no less explicit about the broad objectives of the Fourteenth Amendment, and the intention to make its provisions applicable to all who "may happen to be within the jurisdiction of a State," stating that:

[t]he last two clauses of the first section of the Amendment disable a State from depriving not merely a citizen of the United States, but *any person, whoever he may be*, of life, liberty, or property without due process of law, or from denying to him the equal protection of the laws of the State.

Id. at 214-15.

⁸⁹ *Zadvydas v. Davis*, 533 U.S. 678, 693 (2001).

⁹⁰ See *Wong Wing*, 163 U.S. at 238.

⁹¹ See *Landon v. Plasencia*, 459 U.S. 21, 32-34 (1982); *Johnson v. Eisentrager*, 339 U.S. 763, 770 (1950).

⁹² See 163 U.S. at 238.

within the territory of the United States are entitled to the protection” of the Constitution.⁹³ Further illustrating the notion that the Constitution protects the rights of resident aliens, as well as those of United States citizens, as suggested by constitutional scholars and at least one Framers of the Constitution, the Supreme Court has held that aliens who have come within the territory of the United States and have developed substantial connections with this country have First,⁹⁴ Fifth, and Sixth Amendment rights.⁹⁵

Preceding the Supreme Court’s abovementioned holdings was the decision of the Court of Appeals of Kentucky in *Ely v. Thompson*,⁹⁶ which also supports the scholarly and the judicial approach to the relationship between constitutional rights and non-citizen resident aliens. In *Ely*, a freed African-American, Rhody Ely, sued a justice of the peace and a constable for trespass, assault, battery, and imprisonment.⁹⁷ Ely had apparently “lifted his hand in opposition to a white man”⁹⁸ in violation of a statute that made such conduct by a “negro or mulatto, or Indian, bond or free”⁹⁹ punishable by thirty lashes. A warrant was issued for Ely’s arrest and he was ultimately captured and the constable administered the lashes, following which Ely brought suit.¹⁰⁰

The *Ely* court held that the statute under which Ely was punished violated the State Constitution.¹⁰¹ In doing so, the court first noted that free persons of color were, in some measure,

parties to the political compact Although they have not every benefit or privilege which the [C]onstitution

⁹³ *Id.* (citing *Yick Wo v. Hopkins*, 118 U.S. 356, 369 (1886)) (holding that the equal protection guarantee enshrined in the Equal Protection Clause of the Fourteenth Amendment applied to Chinese aliens). *See also* *United States v. Witkovich*, 353 U.S. 194, 199 (1957) (construing a statute that applied to aliens who were ordered to be deported in a way that would avoid confronting substantive constitutional problems).

⁹⁴ *See* *Bridges v. Wixon*, 326 U.S. 135, 148 (1945); *see also* *Kwong Hai Chew v. Colding*, 344 U.S. 472, 596 n.5 (1953) (citing *Bridges*, 326 U.S. at 161) (“The Bill of Rights is a futile authority for the alien seeking admission for the first time to these shores. But once an alien lawfully enters and resides in this country he becomes invested with the rights guaranteed by the Constitution to all people within our borders.”).

⁹⁵ *Russian Volunteer Fleet v. United States*, 282 U.S. 481, 489 (1931) (holding that the Just Compensation Clause of the Fifth Amendment applied to resident aliens); *Wong Wing*, 163 U.S. at 238 (concluding that resident aliens could invoke the protections of the Fifth and Sixth Amendments).

⁹⁶ 3 Ky. (70 A.K. Marsh.), 1820 WL 1161 (Ky. Dec. 1, 1820).

⁹⁷ *Id.* at *1.

⁹⁸ *Id.* at *2.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at *4.

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secures, yet they have many secured by it Although they are not parties to the compact, yet they are entitled to repose under its shadow, and thus secure themselves from the heated vengeance of the organs of government.¹⁰²

The court went on to state that aliens were, at a minimum, entitled to due process:

Aliens, who sojourn here, and belong to another, and claim nothing of our government, but the right of passage, could not be taken up and hung by a justice of the peace, without a hearing, without an opportunity of proving themselves innocent, and without a jury, even if the legislature, by a solemn act, should direct it to be done.¹⁰³

B. *The Constitutionality of the Gardasil Vaccine Requirement Under the Fifth and Fourteenth Amendments*

The Gardasil vaccine requirement as a prerequisite for naturalization implicates both the Equal Protection and the Due Process Clauses of the Fourteenth Amendment, as well as the Due Process Clause of the Fifth Amendment, which incorporates the Fourteenth Amendment's notion of equal protection. First, the requirement only burdens (financially and otherwise) women and not men, despite the fact that men can also be infected with the HPV virus.¹⁰⁴ Second, the requirement affects only aliens and not United States citizens. Finally, the Gardasil vaccination requirement possibly amounts to a violation of the due process rights of immigrant women because it restricts their right to refuse medical care.

Before the Gardasil immunization requirement can be deemed to violate the Fifth and Fourteenth Amendments, there must be a determination that this mandate constitutes state or federal action, rather than private, non-governmental action.¹⁰⁵ In this case, it is clear that

¹⁰² *Id.* at *5.

¹⁰³ *Id.*

¹⁰⁴ STD Facts, *supra* note 5 (“There are more than 40 HPV types that can infect the genital areas of men and women, including the skin of the penis, vulva (area outside the vagina), and anus, and the linings of the vagina, cervix, and rectum.”).

¹⁰⁵ See *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 349–50 (1974) (“While the principle that private action is immune from the restrictions of the Fourteenth Amendment is well established and easily stated, the question whether particular conduct is ‘private,’ on the one hand, or ‘state action,’ on the other, frequently admits of no easy answer.”); see also *Anthony Cabot & Robert Hannum, Advantage Play and Commercial Casinos*, 74 *MISS. L.J.* 681,

federal action, rather than private action, is present because female immigrants seeking a change of their status to that of permanent resident or naturalized citizen are required by the federal government to present proof of being vaccinated with Gardasil.¹⁰⁶ Further, although federal, not state action is implicated, the Fourteenth Amendment still applies because the Due Process Clause of the Fifth Amendment pertains to the federal government,¹⁰⁷ and the Supreme Court extended the principle of equal protection to actions of the federal government by incorporation in *Bolling v. Sharpe*.¹⁰⁸

1. The Gardasil Vaccination Requirement and the Equal Protection Clause

In considering the effect that the Gardasil vaccination requirement has on female immigrants, as compared to male immigrants, its constitutionality must be evaluated under the Equal Protection Clause of the Fourteenth Amendment (whose equal protection notions are also incorporated into the Fifth Amendment).

The Supreme Court has held that gender-based classifications must be examined through the lens of intermediate review, meaning that such classifications require “an exceedingly persuasive justification” in order to survive constitutional scrutiny.¹⁰⁹ “A statute containing a gender-based classification violates equal protection unless the classification furthers important governmental objectives, and the discriminatory means employed are ‘substantially related’ to the achievement of those governmental objectives.”¹¹⁰

The Court has determined that statutes that are gender-neutral on their face, but have a disproportionately adverse effect on women should be evaluated under the following rubric:

717 (2005) (“State action is necessary to establish a constitutional violation under state and federal equal protection and due process clauses.”); Kevin Cole, *Federal and State “State Action”: The Undercritical Embrace of a Hypercriticized Doctrine*, 24 GA. L. REV. 327, 327 (1990). See generally Daphne Barak-Erez, *A State Action Doctrine for an Age of Privatization*, 45 SYRACUSE L. REV. 1169 (1994); Craig Bradley, *Untying the State Action Knot*, 7 J. CONTEMP. LEGAL ISSUES 223 (1996); Thomas P. Lewis, *The Meaning of State Action*, 60 COLUM. L. REV. 1083 (1960); William W. Van Alstyne & Kenneth L. Karst, *State Action*, 14 STAN. L. REV. 3 (1961).

¹⁰⁶ See *supra* notes 53–56 and accompanying text.

¹⁰⁷ See U.S. CONST. amend. V (“No person shall be . . . deprived of life, liberty, or property, without due process of law.”).

¹⁰⁸ See 347 U.S. 497 (1954), modified, 349 U.S. 294 (1955).

¹⁰⁹ See *Pers. Adm’r of Mass. v. Feeney*, 442 U.S. 256, 273 (1979); see also *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982); *Kirchberg v. Feenstra*, 450 U.S. 455, 461 (1981).

¹¹⁰ *Rainey v. Chever*, 527 U.S. 1044, 119 S.Ct. 2411, 2412 (1999) (quoting 510 S.E.2d 823, 824 (1999)).

The first question is whether the statutory classification is indeed neutral in the sense that it is not gender-based. If the classification itself . . . is not based upon gender, the second question is whether the adverse effect reflects invidious gender-based discrimination. In this second inquiry, impact provides an “important starting point,” but purposeful discrimination is “the condition that offends the Constitution.”¹¹¹

For example, in *Personnel Administrator of Massachusetts v. Feeney*, the statute at issue expressed a preference for hiring veterans for Massachusetts civil service jobs.¹¹² Although the statute was gender-neutral on its face, its effect was to deny women civil service employment. The Supreme Court examined the statute in light of the two-prong test mentioned above, finding that “the definition of ‘veterans’ in the statute has always been neutral as to gender and . . . Massachusetts has consistently defined veteran status in a way that has been inclusive of women who have served in the military . . .”¹¹³ Further, the Court held that the statute’s non-invidious nature was clear from its purpose:

Just as there are cases in which impact alone can unmask an invidious classification, there are others, in which— notwithstanding impact—the legitimate noninvidious purposes of a law cannot be missed. This is one. The distinction made by [the statute] is . . . quite simply between veterans and nonveterans, not between men and women.¹¹⁴

The Court has also held, in *Orr v. Orr*, that a non-gender-neutral statute that was “purportedly designed to compensate for and ameliorate the effects of past discrimination must be carefully tailored.”¹¹⁵ At issue in *Orr* was an Alabama statute providing that, upon divorce, husbands, but not wives, could be required to pay alimony.¹¹⁶ The Court noted that “[w]here . . . the State’s compensatory and ameliorative purposes are as well served by a gender-neutral classification as one that gender classifies . . . , the State cannot be

¹¹¹ *Feeney*, 442 U.S. at 274.

¹¹² *Id.* at 259.

¹¹³ *Id.* at 275.

¹¹⁴ *Id.* (citations omitted).

¹¹⁵ *Orr v. Orr*, 440 U.S. 268, 283 (1979).

¹¹⁶ *Id.* at 270.

permitted to classify on the basis of sex.”¹¹⁷ Thus, the Court held that a “gender-based classification which, as compared to a gender-neutral one, generates additional benefits only for those it has no reason to prefer cannot survive equal protection scrutiny.”¹¹⁸

At issue in the current conflict is the fact that the Act, on its face, is gender-neutral because it requires the production of documentation of vaccination against certain diseases and refers generally to all immigrants who are seeking an adjustment of their status to that of permanent resident.¹¹⁹ However, by adopting the recommendations of ACIP, including its recommendation for Gardasil vaccinations, the statute’s overwhelming effect is to burden female immigrants with the significant expenses and potential side effects associated with the Gardasil vaccine. Though this result is apparently unintentional,¹²⁰ suggesting that there was no invidious intent behind the Act, it is difficult to imagine that the Act satisfies even rational scrutiny review,¹²¹ not to mention intermediate scrutiny review.

Aside from the requirement’s effect on female immigrants, as compared to male immigrants, the constitutionality of the Gardasil vaccination requirement under the Fourteenth Amendment’s Equal Protection Clause and the Fifth Amendment is also suspect because of the impact that this requirement has on non-citizens as compared to United States citizens.

The Supreme Court has established different standards of review for classifications of individuals based on whether they are United States citizens or aliens. When a state establishes these classifications, the

¹¹⁷ *Id.* at 283.

¹¹⁸ *Id.* at 282–83.

¹¹⁹ See 8 U.S.C. § 1182(a)(1)(A)(ii) (2006).

¹²⁰ See *supra* text accompanying notes 69–73.

¹²¹ *Vill. of Willowbrook v. Olech*, 528 U.S. 562, 564–65 (2000) (concluding that the purpose of the Equal Protection Clause is to “secure every person within the State’s jurisdiction against intentional and arbitrary discrimination” and holding that the State’s “irrational and wholly arbitrary” conduct violated the Fourteenth Amendment). If this statute explicitly required girls to receive the Gardasil vaccine as a prerequisite to school entry, scholars argue that it would be unconstitutional under the intermediate scrutiny standard. See Javitt et al., *supra* note 37.

[C]ourts would likely view the goal of preventing cervical cancer as an important public health objective, [but they] would also likely demand that the state justify its decision to burden females with the risks of vaccination, and not males, even though males also contribute to HPV transmission, will benefit from an aggressive vaccination program of females, and also may reduce their own risk of disease through vaccination.

Id.

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Court employs strict scrutiny review,¹²² except in cases where the classifications concern the state's political goals or its political community. In the latter instances, the Court applies the less-demanding rational review standard.¹²³ When the federal government employs classifications distinguishing between citizens and aliens, however, the Court examines them merely through the lens of rational review.¹²⁴ The

¹²² See *Mathews v. Diaz*, 426 U.S. 67, 86 (1976); see also *Sugarman v. Dougall*, 413 U.S. 634, 643 (1973) ("We recognize . . . the State's broad power to define its political community. But in seeking to achieve this substantial purpose, with discrimination against aliens, the means the State employs must be precisely drawn in light of the acknowledged purpose."); *Graham v. Richardson*, 403 U.S. 365, 371-72 (1971).

[T]he Court's decisions have established that classifications based on alienage, like those based on nationality or race, are inherently suspect and subject to close judicial scrutiny. Aliens as a class are a prime example of a "discrete and insular" minority for whom such heightened judicial solicitude is appropriate. Accordingly, . . . "the power of a state to apply its laws exclusively to its alien inhabitants as a class is confined within narrow limits."

Id. (footnotes omitted) (citations omitted).

¹²³ See *Cabell v. Chavez-Salido*, 454 U.S. 432, 438-40 (1982). The Supreme Court has distinguished "between the economic and sovereign functions of government. This distinction has been supported by the argument that although citizenship is not a relevant ground for the distribution of economic benefits, it is a relevant ground for determining membership in the political community." *Id.* at 438. "We recognize a State's interest in establishing its own form of government, and in limiting participation in that government to those who are within 'the basic conception of a political community.'" *Sugarman*, 413 U.S. at 642 (quoting *Dunn v. Blumstein*, 405 U.S. 330, 344 (1972)).

[Strict scrutiny will not apply when dealing]" with matters resting firmly within a State's constitutional prerogatives [and] constitutional responsibility for the establishment and operation of its own government, as well as the qualifications of an appropriately designated class of public office holders." [The Court has] "not abandoned the general principle that some state functions are so bound up with the operation of the State as a governmental entity as to permit the exclusion from those functions of all persons who have not become part of the process of self-government." And in [these] areas, the State's exclusion of aliens need not "clear the high hurdle of 'strict scrutiny,' because [that] would 'obliterate all the distinctions between citizens and aliens, and thus depreciate the historic value of citizenship.'"

The exclusion of aliens from basic governmental processes is not a deficiency in the democratic system but a necessary consequence of the community's process of political self-definition. . . . Aliens are by definition those outside of this community. Judicial incursions in this area may interfere with those aspects of democratic self-government that are most essential to it. This distinction between the economic and political functions of government has, therefore, replaced the old public/private distinction.

Cabell, 454 U.S. at 439-40 (footnote omitted) (citations omitted).

¹²⁴ See *Mathews*, 426 U.S. at 85.

Court has explained the reasoning behind treating state classifications based on citizenship status differently from the same classifications imposed by the federal government by noting that “it is the business of the political branches of the Federal Government, rather than that of either the States or the Federal Judiciary, to regulate the conditions of entry and residence of aliens.”¹²⁵

Commentators question this approach, which arguably arises out of the Court’s belief that “the political branches of the federal government need a great deal of flexibility in dealing with noncitizens.”¹²⁶ These commentators contend that “the Court ought to employ strict scrutiny to ensure that the federal government is not engaged in invidious discrimination against this discrete and insular minority, and that its lines are narrowly drawn to serve compelling state interests.”¹²⁷

Michael Scaperlanda, in his Article *Illusions of Liberty and Equality: An “Alien’s” View of Tiered Scrutiny, Ad Hoc Balancing, Governmental Power, and Judicial Imperialism*, asked the following questions about the Supreme Court’s approach to deciding cases in this arena: “[s]o, why the shift in standard? Are aliens less likely to suffer invidious discrimination at the hands of the federal government? Are our national leaders more virtuous than our state leaders, and, therefore, in less need of scrutiny from the judiciary? Or, is something else at play?”¹²⁸

In the issue at hand, the federal government established a classification between aliens and United States citizens. As a result, this classification would likely be subjected to the lowest level of scrutiny afforded to these types of classifications—rational level scrutiny.

A division by a State of the category of persons who are not citizens of that State into subcategories of United States citizens and aliens has no apparent justification, whereas, a comparable classification by the Federal Government is a routine and normally legitimate part of its business. . . . [W]hereas the Constitution inhibits every State’s power to restrict travel across its own borders, Congress is explicitly empowered to exercise that type of control over travel across the borders of the United States.

Id.

¹²⁵ *Id.* at 84.

¹²⁶ See Michael A. Scaperlanda, *Illusions of Liberty and Equality: An “Alien’s” View of Tiered Scrutiny, Ad Hoc Balancing, Governmental Power, and Judicial Imperialism*, 55 CATH. U. L. REV. 5, 16 (2005); see also *Fong Yue Ting v. United States*, 149 U.S. 698, 713 (1893) (“The power to exclude or to expel aliens, being a power affecting international relations, is vested in the political departments of the government.”); Hiroshi Motomura, *Immigration Law After a Century of Plenary Power: Phantom Constitutional Norms and Statutory Interpretation*, 100 YALE L.J. 545, 563 (1990) (“Institutional constraints, especially the judiciary’s sensitivity to its limited factfinding capability and attenuated electoral responsibility, make courts reluctant to issue a constitutional command to the political branches of government.”).

¹²⁷ Scaperlanda, *supra* note 126, at 17.

¹²⁸ *Id.* at 18.

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Nevertheless, as was noted above, there is some question regarding whether the Gardasil immunization requirement imposed only upon immigrants seeking to become permanent residents and, eventually, naturalized citizens would be considered rational, as opposed to wholly arbitrary.¹²⁹ After all, even the CDC has acknowledged that this requirement is a completely unintended consequence arising out of the revision of the list of vaccinations recommended for United States citizens by the ACIP.¹³⁰

2. The Gardasil Vaccination Requirement and the Due Process Clauses

The Gardasil vaccination requirement potentially deprives female immigrants of their life, liberty, or property, as it implicates their right to refuse medical treatment by forcibly exposing them to a vaccine that may not be sufficiently tested and may produce adverse affects in the future, which effectively turns the female immigrants into unwitting clinical test subjects. Thus, an analysis of the requirement under the Due Process Clauses of the Fifth and Fourteenth Amendments is appropriate.

Generally, aliens who have entered the United States, whether lawfully or unlawfully, are entitled to the protections of the Fifth Amendment and are afforded the same due process rights as United States citizens.¹³¹ The Fifth Amendment provides that the federal government shall not deprive a person of "life, liberty, or property, without due process of law."¹³² "The term due process . . . refer[s] to either procedural due process[,] . . . the guarantees of procedural fairness in the justice system, or substantive due process[,] . . . the general proposition that legislation must be fair and reasonable in content and cannot arbitrarily deprive a citizen of life, liberty, or property."¹³³

The Supreme Court attaches an expansive meaning to the notion of "liberty," defining it to denote:

not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of

¹²⁹ See *supra* text accompanying notes 120–21.

¹³⁰ See *supra* text accompanying note 70; see also *supra* text accompanying note 56.

¹³¹ See *Zadvydas v. Davis*, 533 U.S. 678, 693 (2001) ("[T]he Due Process clause applies to all 'persons' within the United States, including aliens, whether their presence here is lawful, unlawful, temporary, or permanent."); *Kwong Hai Chew v. Colding*, 344 U.S. 590, 596 (1953); *Capric v. Ashcroft*, 355 F.3d 1075, 1087 (7th Cir. 2004); *Ramirez-Alejandre v. Ashcroft*, 319 F.3d 365, 380 (9th Cir. 2003).

¹³² U.S. CONST. amend. V.

¹³³ Ronald J. Stay, Comment, *Cryptic Controversy: U.S. Government Restrictions on Cryptography Exports and the Plight of Philip Zimmermann*, 13 GA. ST. U. L. REV. 581, 593 (1997).

the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.¹³⁴

The right to liberty specifically or the right to due process generally, may be curtailed by legislative action that is not arbitrary and that has a reasonable relation to some legitimate governmental purpose.¹³⁵ To determine the reasonableness of the curtailment of an individual's liberty interest, the Court balances the relevant liberty interest against the pertinent state interest.¹³⁶ The Court has repeatedly affirmed the notion that "the right of every individual to the possession and control of his own person, free from all restraint [and] interference of others,"¹³⁷ is "so rooted in the traditions and conscience of our people,"¹³⁸ "as to be ranked as one of the fundamental liberties protected by the 'substantive' component of the Due Process Clause."¹³⁹ Indeed, the Court noted as early as 1891 that "[t]o compel . . . a woman, to lay bare the body, or to submit it to the touch of a stranger . . . is an indignity, an assault, and a trespass; and no order of process, commanding such an exposure or submission, was ever known to the common law . . ."¹⁴⁰

In the vaccination context, the Supreme Court has held that "when the health concerns of the larger community are at stake, the state may indeed infringe upon individual rights."¹⁴¹ The Court has noted, however, "that certain protections for the individual must be accommodated consistent with liberty principles under the Due Process Clause of the Fourteenth Amendment."¹⁴² By approving vaccination requirements with respect to diseases such as smallpox, the Court has

¹³⁴ *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

¹³⁵ *Id.* at 399–400.

¹³⁶ *See Cruzan v. Dir., Miss. Dep't of Health*, 497 U.S. 261, 279 (1990).

¹³⁷ *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

¹³⁸ *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934), *overruled in part*, *Malloy v. Hogan*, 378 U.S. 1 (1964).

¹³⁹ *Newman v. Sathyavaglswaran*, 287 F.3d 786, 789 (9th Cir. 2002). *See also* *Schmerber v. California*, 384 U.S. 757, 772 (1966) ("The integrity of an individual's person is a cherished value of our society."); *Rochin v. California*, 342 U.S. 165, 174 (1952) (describing unauthorized physical invasions of the body as being "offensive to human dignity").

¹⁴⁰ *Botsford*, 141 U.S. at 252.

¹⁴¹ Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 384 (2004).

¹⁴² *Id.* at 384 n.218.

acknowledged that compulsory vaccination may only be appropriate when public health concerns are sufficiently implicated.¹⁴³

In *Jacobson v. Massachusetts*, the Court held that “a state’s police powers ‘must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and safety.’”¹⁴⁴ The *Jacobson* Court was not asked to consider, however, “whether there was a dispute as to the efficacy of the vaccine. Nor was it asked to determine, in this particular instance, whether the smallpox vaccine would harm th[e] particular plaintiff.”¹⁴⁵ As a result, “while *Jacobson* ‘stands firmly for the proposition that police powers authorize states to compel vaccination for the public good,’ it also indicates that ‘government power must be exercised reasonably to pass constitutional scrutiny.’”¹⁴⁶ Subsequently, the Court upheld *Jacobson* through its decision in *Zucht v. King*.¹⁴⁷ It again stated, however, that the exercise of the broad discretion accorded to the states and the federal government in the context of compulsory vaccination is appropriate only when there is a need to protect the public health.¹⁴⁸

Although the HPV vaccine protects against a disease that can be deadly, it is still different than the vaccines whose compulsory use has been approved by the courts, including the Supreme Court, in the face of the Due Process Clauses of the Fifth and Fourteenth Amendments. Specifically, the HPV vaccine does not satisfy the two principles articulated by the *Jacobson* Court in the course of its approval of the small pox vaccine. First:

HPV infection presents no public health necessity, as that term was used in the context of *Jacobson*. While non-sexual transmission routes are theoretically

¹⁴³ See *id.* at 384. Even when the Supreme Court has approved of such vaccine mandates, it has frequently allowed for exemptions for those with adverse medical conditions. *Jacobson v. Massachusetts*, 197 U.S. 11, 12, 30 (1905). Where exemptions are not provided either for philosophical or for religious reasons, various courts have held that individuals’ constitutional rights may be restricted by compulsory vaccinations “in the name of the public welfare.” Calandrillo, *supra* note 141, at 385.

¹⁴⁴ Emily Hammond Meazell, *Scientific Avoidance: Toward More Principled Judicial Review of Legislative Science*, 84 IND. L.J. 239, 263 (2009) (citing *Jacobson*, 197 U.S. at 25).

¹⁴⁵ *Id.* at 264 (citing *Jacobson*, 197 U.S. at 30–31). The Court left open the possibility that the statute mandating a smallpox vaccination might be unconstitutional in an as-applied challenge where an adult could show that the vaccine would cause serious bodily harm in her particular case. *Jacobson*, 197 U.S. at 39.

¹⁴⁶ See Javitt et al., *supra* note 37, at 388–89 (citing Lawrence O. Gostin & James G. Hodge, *The Public Health Improvement Process in Alaska: Toward a Model Public Health Law*, 17 ALASKA L. REV. 77, 89 (2000)).

¹⁴⁷ See 260 U.S. 174, 177 (1922).

¹⁴⁸ See *id.*

possible, they have not been demonstrated. Like other sexually transmitted diseases which primarily affect adults, it is not immediately life threatening; as such, cervical cancer, if developed, will not manifest for years if not decades. Many women will never be exposed to the cancer-causing strains of HPV; indeed the prevalence of these strains in the U.S. is quite low. Furthermore, many who are exposed will not go on to develop cervical cancer.¹⁴⁹

Further, for the above noted reason, there is no “reasonable relationship” between the HPV vaccine mandate in immigrants and the goal of protecting the public health.¹⁵⁰ Although it is possible that immigrant women coming from developing countries may have a higher chance of carrying the HPV virus, Gardasil does not cure HPV and, therefore, likely does not address this problem. Moreover, a better resolution would be to institute HPV screening tests to attempt to minimize the incidence of HPV among immigrant women without the accompanying costs and side-effects of Gardasil. Finally, the fact that the Gardasil vaccination requirement in the immigrant context came about essentially by accident counsels against the argument that there is a rational link between the compulsory HPV vaccination of female immigrants and the government’s concern for the public health. Thus, the government will have difficulty demonstrating that its interests in protecting the public health are strong enough to outweigh the right of immigrant women to refuse medical treatment.¹⁵¹

VI. CONCLUSION

Although the Gardasil vaccine may prevent women (and men) from exposure to a deadly disease, Gardasil has not yet been extensively

¹⁴⁹ Javitt et al., *supra* note 37, at 389.

¹⁵⁰ *See id.*

¹⁵¹ *See id.* at 392. The authors noted that, in the context of mandatory HPV vaccination as a prerequisite to school attendance:

[m]andated HPV laws interfere with the right of girls to refuse medical treatment, and therefore could be challenged under the Due Process Clause . . . even if courts uphold government mandates as consistent with the Due Process and Equal Protection clauses, such mandates remain troubling in light of inequalities imposed by sex-based mandates and the liberty interests that would be compromised by HPV mandates, therefore placing deeply cherished national values at risk.

Id.

studied or tested. Its use has also been accompanied by a myriad of side effects, including death. The vaccine is only recommended for females between the ages of eleven to twenty-six who are United States citizens. It is, however, required for immigrant women who wish to obtain permanent resident status and eventually become naturalized citizens—a result that the CDC admits is wholly unintentional. As this Article argues, because the Gardasil mandate raises significant social, economic, and constitutional issues, this vaccine must be re-classified as being an optional, rather than a mandatory part of female immigrants' process of becoming permanent residents and, eventually, United States citizens.