

5-1-2013

# A Recommendation Report on CDC Immunization Guidelines to Determine Immigrant Vaccination Requirements for Women, With the Use of Mandated HPV Vaccine as a Case Study

Regina Veronica Ram

Follow this and additional works at: [https://scholarship.shu.edu/student\\_scholarship](https://scholarship.shu.edu/student_scholarship)

---

## Recommended Citation

Ram, Regina Veronica, "A Recommendation Report on CDC Immunization Guidelines to Determine Immigrant Vaccination Requirements for Women, With the Use of Mandated HPV Vaccine as a Case Study" (2013). *Law School Student Scholarship*. 292.  
[https://scholarship.shu.edu/student\\_scholarship/292](https://scholarship.shu.edu/student_scholarship/292)

**A RECOMMENDATION REPORT ON CDC IMMUNIZATION GUIDELINES TO DETERMINE IMMIGRANT VACCINATION REQUIREMENTS FOR WOMEN, WITH THE USE OF MANDATED HPV VACCINE AS A CASE STUDY**

*Regina Ram, MPH*

INTRODUCTION .....	1
I. LEGAL PRECEDENTS FOR VACCINATION .....	3
II. HPV VACCINE CASE STUDY .....	5
A. <i>Overview</i> .....	6
B. <i>Human papillomavirus (HPV)</i> .....	8
C. <i>Gardasil Vaccine</i> .....	9
1. <i>State Response</i> .....	9
2. <i>Controversy and Concern Over Mandating Gardasil</i> .....	10
3. <i>Alternative State Responses</i> .....	13
4. <i>Mandate for Female Immigrants</i> .....	14
5. <i>CDC Response and Current Guidelines</i> .....	16
III. CRITIQUE AND RECOMMENDATIONS .....	17
A. <i>Effect of Gender on Vaccine Immunization</i> .....	17
B. <i>Further Critique</i> .....	20
C. <i>Recommendations</i> .....	20
D. <i>Alternative Recommendations</i> .....	23
IV. CONCLUSIONS AND FUTURE RELEVANCE .....	26

INTRODUCTION

The intersection of health and gender in the context of vaccine requirements for immigrants is complex. Vaccinations that are simply recommended for the American public by the Centers for Disease Control and Prevention (CDC) are required for immigrants in order to pass medical exams during the immigration process.<sup>1</sup> Immigrants are left weighing the concerns of taking the vaccines against their desire to seek American citizenship, leaving them without the opportunity for true informed consent. This issue became more salient in 2008-2009 when

---

<sup>1</sup> *Vaccination Requirements*, USCIS (Mar. 5, 2010), <http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnextoid=3384cc5222ff5210VgnVCM100000082ca60aRCRD&vgnnextchannel=6abe6d26d17df110VgnVCM1000004718190aRCRD>.

women immigrants were required to show proof of vaccine for human papillomavirus (HPV), a vaccine that remains highly controversial in the United States.<sup>2</sup> CDC responded with amended laws that removed HPV from the vaccine list, but did not create criteria to protect women immigrants against future requirements for vaccines that are specific to one gender.<sup>3</sup> This paper argues that current immunization laws for immigrants still ignore crucial gender differences and may place an undue burden on women seeking American citizenship. The paper proposes that CDC revise the recommended vaccine requirement criteria while considering substantive equality principles in order to avoid future injustice.

The paper will present the following arguments. Part I examines the legal historical use of vaccines as a public health and safety measure, and argues that vaccine use is highly advantageous. Vaccination requirements for immigrants are justified by public health concerns. However, Part II explains the recent case of how HPV vaccines were inadvertently mandated for immigrant women because of previous CDC immunization guidelines. This difference, based on gender, discriminated against women in the immigration process. The CDC promulgated new vaccination guidelines as a result of outcry by public groups.<sup>4</sup> Part III critiques these current vaccination guidelines as still lacking consideration of important gender differences. It also provides recommendations for how CDC can improve the current vaccination laws for immigrants to provide equity between men and women. Finally, Part IV draws conclusions and highlights the future relevance of sex-based vaccines.

---

<sup>2</sup> Letter from Priscilla Huang, Nat'l Asian Pac. Am. Women's Forum, to Thomas R. Frieden, Acting Dir., CDC (Aug. 10, 2009) (*available at* [www.aila.org/content/default.aspx?docid=29746](http://www.aila.org/content/default.aspx?docid=29746)).

<sup>3</sup> *New Vaccination Criteria for U.S. Immigration*, CDC (Oct. 20, 2010), <http://www.cdc.gov/immigrantrefugeehealth/laws-regs/vaccination-immigration/revised-vaccination-immigration-faq.html>.

<sup>4</sup> *Id.*

## I. LEGAL PRECEDENTS FOR VACCINATION

The history of vaccine use as a public health measure is well established, and the benefits of vaccines are irrefutable.<sup>5</sup> Vaccine use is considered to be one of the greatest public health achievements of our time for the number of lives it has saved,<sup>6</sup> and vaccines are generally required for school entry though exceptions exist.<sup>7</sup>

On a federal level, the secretary of the U.S. Department of Health and Human Services (HHS) has the right to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the states or possessions.<sup>8</sup> This power was established through the Public Health Service Act of 1946, and includes the power to restrict the entry of immigrants due to public health reasons.<sup>9</sup>

Furthermore, the power of states to mandate vaccines has been fairly well established in the U.S. through case law.<sup>10</sup> That power, however, is contingent upon several criteria. In one of the seminal cases in vaccine law, *Jacobson v. Massachusetts*, the court held that a state vaccine statute against smallpox was a valid and necessary public health measure.<sup>11</sup> It considered the mandate a legitimate and constitutional exercise of state police power, and justified the limitation of individual freedom through four reasons- 1) the law met the means-ends test (there was a

---

<sup>5</sup> *History of Vaccine Safety*, CDC (Feb. 8, 2011), [http://www.cdc.gov/vaccinesafety/vaccine\\_monitoring/history.html](http://www.cdc.gov/vaccinesafety/vaccine_monitoring/history.html).

<sup>6</sup> *Id.*

<sup>7</sup> *Zucht v. King*, 260 U.S. 174 (1922) (holding that local government may mandate vaccination as a prerequisite for public school attendance); *see generally* James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, KY. L.J. 90, 831-90 (2001) (exemptions are often made for children with medical contra-indications to vaccines, children with established religious beliefs that are contrary to vaccination, and home-schooled children who are not part of the public school system).

<sup>8</sup> Public Health Service, 42 U.S.C. Chapter 6A (2006).

<sup>9</sup> *Id.*

<sup>10</sup> *See generally* Ching Ping Ang, Joseph Woplin & Elisha Baron, *Recent Developments in Health Law- Federal Law Required HPV Vaccine for Green Card Applicants: Valid Exercise of State Police Powers?*, 37 J.L. MED. & ETHICS 149, 149-59 (2009).

<sup>11</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

reasonable relationship between the intervention and the achievement of a legitimate public health measure), 2) there was legitimate public health necessity (it was not an unreasonable or arbitrary measure), 3) the compulsory vaccination was proportional in burden and benefit (the burden imposed on the individual was proportionate to the public health) and 4) there was a medical exemption for being unfit (having some physical condition that posed a particular risk for adverse effects).<sup>12</sup> In essence, the holding required that limiting individual rights due to public health must be necessary, reasonable and proportionately balanced between the public good and the imposition of personal autonomy.<sup>13</sup>

*Wong Wai v. Williamson* was another important vaccine case that preceded *Jacobson*, and is especially useful precedent because it struck down a law requiring vaccines for a particular racial group.<sup>14</sup> In this case, the court considered a San Francisco ordinance requiring that Chinese people be placed under quarantine and vaccinated for bubonic plague.<sup>15</sup> The court declared the law unconstitutional, and held that requiring a certain vaccination was not a valid exercise of state police powers when it was applied to a group of individuals with no particular susceptibility to the disease and that posed no heightened threat to the public.<sup>16</sup>

While case law supports federal and state ability to mandate vaccines, this police power justification is only commonly used to support compulsory vaccinations for school-aged children.<sup>17</sup> Vaccines remain generally recommended for adults, and immunization policy focuses

---

<sup>12</sup> Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUBLIC HEALTH 576, 576-81 (Apr. 2005).

<sup>13</sup> *Jacobson*, *supra* note 11.

<sup>14</sup> *Wong Wai v. Williamson et al.*, 103 F. 1 (C.C.D. 1900).

<sup>15</sup> Chuck Marcus, *Anti-Chinese Laws*, U. OF CAL. HASTINGS C. OF THE L. LIBRARY (2001), <http://librarysource.uchastings.edu/library/research/special-collections/wong-kim-ark/laws3.htm>.

<sup>16</sup> *Williamson*, *supra* note 14.

<sup>17</sup> Hodge & Gostin, *supra* note 7.

most commonly on flu and pneumonia immunizations for older adults.<sup>18</sup> The recommended Adult Immunization Schedule created by CDC includes vaccines such as Hepatitis B, tetanus and varicella, but these apply only to distinct at-risk populations and adults in certain occupations.<sup>19</sup>

Mandatory vaccinations in adults therefore remain rare, and legislatures have not often tried to mandate vaccines in this population. In fact, the New York State Health Commissioner Richard F. Daines was met with massive protest when he suggested mandatory vaccination of healthcare workers for the H1N1 swine flu.<sup>20</sup> The fact that vaccine mandates are uncommon for adults, and that the ones required for school-aged children are non-discriminatory and apply to both boys and girls, a vaccine mandate for only women immigrants ages 11 through 26 sparked heated debate.

## II. HPV VACCINE CASE STUDY

This section provides a case study on the the vaccine for Human papillomavirus (HPV), a disease commonly known as cervical cancer. First, Part A provides a general explanation of the debate over mandating this vaccine for immigrant women that occurred from 2008 to 2009. Part B provides a review of HPV, offers statistics relating to the disease, and explains the disease burden. Part C focuses on the specific vaccine for HPV, Gardasil. This part further evaluates state law response to the vaccine when it was first approved for use in females, the controversy and concern over mandating the vaccine in the U.S., and the alternative responses taken by many

---

<sup>18</sup> *Immunizations*, NAT'L CONF. OF ST. LEGISLATURES (Apr. 2011), <http://www.ncsl.org/issues-research/health/immunizations-policy-issues-overview.aspx>.

<sup>19</sup> *Adult Immunization Schedule*, CDC (2012), <http://www.cdc.gov/vaccines/schedules/hcp/adult.html> (Varicella is the scientific name for chickenpox).

<sup>20</sup> *Mandatory Flu Vaccine for Health Care Workers*, N.Y. ST. DEP'T OF HEALTH (Sep. 24, 2009), [http://www.health.ny.gov/press/releases/2009/2009-09-24\\_health\\_care\\_worker\\_vaccine\\_daines\\_oped.htm](http://www.health.ny.gov/press/releases/2009/2009-09-24_health_care_worker_vaccine_daines_oped.htm); Alexandra M. Stewart, *Mandatory Vaccination of Health Care Workers*, 361 NEW ENG. J. MED. 2015; 2015-17 (Nov. 19, 2009).

states. Part C further explains the specific mandate for female immigrants, and the response by CDC in creating new guidelines for immigrant vaccination requirements.

#### *A. Overview*

In July 2008, U.S. Citizenship and Immigration Services (USCIS) amended the list of vaccination requirements for those seeking permanent legal status in the country.<sup>21</sup> The updated guidelines, which went into effect on August 1, 2008, required age appropriate vaccinations of HPV, Rotavirus, Hepatitis A, Meningococcal, and Zoster.<sup>22</sup> The new vaccinations were added to the I-693 Report of Medical Examination and Vaccination Record, a form that is required for all applicants seeking U.S. citizenship.<sup>23</sup> These new vaccinations went alongside previous requirements including vaccinations against mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, influenza type B and hepatitis B.<sup>24</sup>

The updates to the vaccination list resulted directly from CDC vaccine recommendations made for U.S. citizens at the time.<sup>25</sup> Under Section 212 of the Immigration and Nationality Act,<sup>26</sup> all immigrants or those applying for legal status must provide documentation of vaccination for all CDC Advisory Committee for Immunization Practices (ACIP) recommended vaccines.<sup>27</sup>

ACIP is a group of 15 members considered to be experts in fields associated with

---

<sup>21</sup> *USCIS Changes Vaccination Requirements To Adjust Status To Legal Permanent Resident*, USCIS (July 24, 2008), <http://www.uscis.gov/portal/site/uscis/menuitem.5af9bb95919f35e66f614176543f6d1a/?vgnextoid=902252b10f45b110VgnVCM1000004718190aRCRD&vgnnextchannel=1958b0aaa86fa010VgnVCM10000045f3d6a1RCRD>.

<sup>22</sup> *Id.* (These viruses and bacteria do not have common names, with the exception Zoster, commonly known as Shingles. Each of the vaccines listed protect from serious disability or life-threatening diseases).

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Anne Kimbol, *The HPV Vaccine Debate Meets the International Stage*, HEALTH L. PERSP. (Oct. 2008), available at <http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>.

<sup>26</sup> Inadmissible aliens, 8 U.S.C. 1182 (2006); *Criteria for Vaccination Requirements for U.S. Immigration Purposes*, 74 Fed. Reg. 66 (Apr. 8, 2009), available at <http://www.thefederalregister.com/d.p/2009-04-08-E9-7934>.

immunization.<sup>28</sup> The committee is selected by the Secretary of HHS to provide advice and guidance to the Secretary for Health, the Assistant Secretary for Health, and the CDC.<sup>29</sup> Specifically, ACIP's role is to develop written recommendations for routine vaccine administration including age for vaccine, number of doses and dosing interval, and precautions and contraindications.<sup>30</sup>

The 2008 changes required a mandatory 6-month course of the HPV vaccine Gardasil for all females ages 11-26 that were seeking U.S. citizenship.<sup>31</sup> ACIP had recommended this vaccine shortly after its approval in 2006, and it became the only vaccine added to the I-693 form that was not meant to fight infectious disease transmitted by the respiratory route.<sup>32</sup> Over 100 prominent groups, including the American Congress of Obstetricians and Gynecologists, the American Immigration Lawyers Association, and the Planned Parenthood Federation of America, issued formal statements opposing the update.<sup>33</sup> Specifically, these groups sought to speak out against the requirements on the basis of discrimination and undue burden for female immigrants.<sup>34</sup>

---

<sup>27</sup> *Advisory Committee on Immunization Practices (ACIP)*, CDC (Oct. 28, 2009), <http://www.cdc.gov/vaccines/recs/ACIP/default.htm>.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> Kimbol, *supra* note 25; *See infra* Part III.C for a further explanation of the Gardasil vaccine.

<sup>32</sup> *Id.* (every other vaccine listed prevents a contagious disease that is transmitted through the air and can be contracted by inhaling an airborne droplet of the pathogen).

<sup>33</sup> *ACOG Joins Opposition to Mandatory HPV Vaccine Requirement for Immigrant Girls and Women*, AM. CONGRESS OF OBSTETRICS AND GYNECOLOGY (Feb. 2, 2009), [http://www.acog.org/from\\_home/publications/press\\_releases/nr02-02-09.cfm](http://www.acog.org/from_home/publications/press_releases/nr02-02-09.cfm).

<sup>34</sup> *Id.*



*B. Human papillomavirus (HPV)*

HPV is the most common sexually transmitted infection (STI) in the U.S. at about 6 million new cases a year.<sup>35</sup> While not every strain is highly virulent, two particular HPV strains can create cellular abnormalities leading to genital warts and cervical cancer.<sup>36</sup> There are an estimated 12,000 new cases of cervical cancer per year, with 4,000 annual deaths.<sup>37</sup> There is evidence that HPV rates in the U.S. disproportionately affect those of lower socioeconomic status, immigrants, and the uninsured.<sup>38</sup>

Worldwide, cervical cancer is the third most common cancer in women, with over 500,000 new cases per year.<sup>39</sup> At least 80% of these cases happen in low-income or middle-income countries and the highest disease incidence is seen in women from Central America and Southern Africa, as well as South America and Southern Asia.<sup>40</sup> The disproportionate impact may be caused by lack of access to Pap smears that detect HPVs and are considered a strong preventative measure for cervical cancer.<sup>41</sup> The appearance of HPVs on a Pap smear is not absolutely demonstrative of cervical cancer.<sup>42</sup> This is because Pap smears will display the existence of every HPV strain, most of which are harmless, and only two specific HPV strains

---

<sup>35</sup> *Overview and Fast Facts*, AM. SOC. HEALTH ASS'N (2012), <http://www.ashastd.org/std-sti/hpv/overview-and-fast-facts.html>.

<sup>36</sup> *Id.*

<sup>37</sup> *Cervical Cancer Statistics*, CDC (Apr. 30, 2012), <http://www.cdc.gov/cancer/cervical/statistics/>.

<sup>38</sup> *Id.*

<sup>39</sup> *Cervical Cancer Incidence and Mortality Worldwide in 2008 Summary*, INT'L AGENCY FOR RES. ON CANCER (2010), <http://globocan.iarc.fr/factsheets/cancers/cervix.asp>.

<sup>40</sup> Jacqueline Sherris, Cristina Herdman & Christopher Elias, *Cervical Cancer in the Developing World*, 175 W. J. MED. 231, 231-233 (Oct. 2001).

<sup>41</sup> Jennifer L. Young, *HPV Vaccine: Ethics of the School Mandate*, AM. PUB. HEALTH ASS'N 135th Annual Meeting: Select Presentations, May 2008, <http://www.medscape.org/viewarticle/574088>.

<sup>42</sup> *Id.*

can cause cervical cancer.<sup>43</sup> For this reason, a specific HPV DNA test is used in conjunction with a positive Pap smear in order to confirm the disease.<sup>44</sup>

### *C. Gardasil Vaccine*

The Gardasil vaccine for HPV is manufactured by Merck & Co., and received Food and Drug Administration (FDA) Approval in June 2006.<sup>45</sup> It is approved for use by females ages 9-26 for the prevention of cervical cancer and genital warts caused by HPV types 6, 11, 16 and 18.<sup>46</sup> In particular, HPV types 16 and 18 are responsible for 70% of cervical cancers.<sup>47</sup> The vaccine is administered by three injections over a 6-month period.<sup>48</sup> In late 2009, the vaccine was also approved for use in males ages 9 through 26 for the prevention of genital warts caused by HPV types 6 and 11.<sup>49</sup>

#### 1. State Response

Merck began an aggressive marketing campaign after Gardasil's approval, and twenty-four states and the District of Columbia introduced legislation mandating the vaccine for girls ages 9 through 14.<sup>50</sup> Despite the flurry of legislation attempting to make the HPV vaccine compulsory, states turned decisively away from mandating the vaccine and only the District of

---

<sup>43</sup> AM. SOC. HEALTH ASS'N *supra* note 35.

<sup>44</sup> *Id.*

<sup>45</sup> *Vaccines, Blood & Biologics- Gardasil*, FDA (Oct. 21, 2011), <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042>.

<sup>46</sup> *Id.*

<sup>47</sup> Jane J. Kim & Sue J. Goldie, *Health and Economic Implications of HPV Vaccination in the United States*, 359 NEW ENG. J. MED. 821, 821-832 (Aug. 21, 2008); Laurie Udesky, Push to mandate HPV vaccine triggers backlash in USA, 369 LANCET 979, 979-980 (Mar. 24, 2007).

<sup>48</sup> FDA, *supra* note 45.

<sup>49</sup> *Id.*

<sup>50</sup> Udesky, *supra* note 47; Gail Javitt, Deena Berkowitz, & Lawrence O. Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384 (2008).

Columbia and Virginia actually approved HPV vaccine mandates.<sup>51</sup> Virginia introduced legislation to eliminate the mandate in January 2011.<sup>52</sup> The marked change in state opinion may be attributed to the controversy over Gardasil's safety and efficacy, the concern of mandating a childhood vaccine for an STI, and the risk of public backlash against a compulsory HPV vaccination.

## 2. Controversy and Concern Over Mandating Gardasil

Critics of the HPV vaccine mandate focus on the lack of data regarding Gardasil's efficacy.<sup>53</sup> The FDA completed a six-month priority review of Gardasil that included four studies with 21,000 women between the ages of sixteen and twenty-six.<sup>54</sup> Opponents consider the priority review to be an inadequate sample size with a limited period of follow-up.<sup>55</sup> Since the duration of the study was not long enough for cervical cancer to develop, researchers considered the prevention of cervical precancerous lesions to be equivalent to the prevention of cervical cancer.<sup>56</sup>

Clinicians argue that the duration of the vaccine-induced immunity remains unclear.<sup>57</sup> HPV antibodies (which are created by the immune system to help respond to the disease) are not always detected in the blood serum of women, even when women have cases of naturally

---

<sup>51</sup> In both D.C. and Virginia, the vaccine policy developed was linked to 6<sup>th</sup> grade school vaccinations for girls and was provided free of cost. There was also an opt-out clause for parents with or without a signed waiver, respective to each state (James Colgrove, Sara Abiola & Michelle Mello, *HPV Vaccination Mandates — Lawmaking Amid Political and Scientific Controversy*, 363 NEW ENG. J. MED. 785 (2010)).

<sup>52</sup> Young, *supra* note 41; *Eliminating requirement for HPV vaccine*: 2010 VA H.B. 686 (NS) Jan. 13, 2010.

<sup>53</sup> Colgrove et al., *supra* note 51.

<sup>54</sup> *FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus*, FDA (Jun. 18, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm>.

<sup>55</sup> Elizabeth R. Sheyn, *An Accidental Violation: How Required Gardasil Vaccinations for Female Immigrants to the United States Contravene International Law*. 88 NEB. L. REV. 524 (2009).

<sup>56</sup> *Id.*; The average follow-up period for Gardasil during clinical trials was 15 months after the third dose of the vaccine. See Javitt et al., *supra* note 50.

occurring HPV infection.<sup>58</sup> This suggests that blood serum measurements of HPV antibodies may not accurately represent HPV infection- it may be impossible for tests to determine if the vaccine is creating HPV antibodies and providing protection.<sup>59</sup>

While current data may suggest that the vaccine is safe, the long-term protection of the vaccine is yet unknown. CDC and FDA have utilized the Vaccine Adverse Event Reporting System (VAERS) to monitor the safety of the Gardasil vaccine after its approval.<sup>60</sup> As of February 14, 2011, an estimated 33 million doses of Gardasil have been distributed in the United States and there have been a total of 18,354 adverse events.<sup>61</sup> Approximately eight percent of these adverse events were serious and included blood clots, Guillain-Barré syndrome, hospitalization, and death.<sup>62</sup>

Opponents also point out that mandating Gardasil, a vaccine for an STI, is a clear departure from traditional compulsory vaccinations.<sup>63</sup> Critics of a mandated HPV vaccination argue that HPV does not present a public health necessity and is not reasonably related to school entry.<sup>64</sup> Unlike other diseases for which there are mandated vaccines, HPV is not highly contagious through casual contact and there is no significant morbidity or mortality that occurs shortly after exposure.<sup>65</sup> Current research has demonstrated transmission only through sexual contact and has shown that only some strains of HPV lead to cervical cancer, a disease which

---

<sup>57</sup> Sheyn, *supra* note 55.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Vaccine Adverse Event Reporting System (VAERS)*, FDA (Aug. 6, 2009), <http://www.fda.gov/NewsEvents/Testimony/ucm115058.htm>.

<sup>61</sup> *Reports of Health Concerns Following HPV Vaccination*, CDC (Feb. 17, 2011), <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/gardasil.html#asterisk> (Guillain-Barré syndrome is a nervous system disorder that can lead to paralysis).

<sup>62</sup> *Id.*

<sup>63</sup> Sheyn, *supra* note 55.

<sup>64</sup> Javitt et al., *supra* note 50.

takes years to progress.<sup>66</sup> Further, because sexual contact is the only known route of transmission, children are not at risk of catching HPV from being in proximity to one another in a classroom setting. The Gardasil vaccine is therefore unreasonably related to school admission.

Finally, opponents of a HPV vaccine mandate argue that it would unjustifiably restrict parental autonomy.<sup>67</sup> Parents have a fundamental right under the due process clause of the 14<sup>th</sup> amendment to raise their children as they see fit.<sup>68</sup> This right, referred to as the Parental Rights Doctrine, has been supported by case law.<sup>69</sup> The most recent case supporting this constitutional right is *Troxel v. Granville*, where the court held that “the Due Process Clause of the Fourteenth Amendment protects the fundamental right of parents to make decisions concerning the care, custody, and control of their children.”<sup>70</sup> Earlier case law that articulated this fundamental liberty interest includes *Meyer v. Nebraska*, and *Pierce v. Society of Sisters*.<sup>71</sup> *Meyer* recognized the natural duties of a parent, while *Pierce* noted that parents have the right and duty to prepare their children for life.<sup>72</sup>

Parental autonomy presents a strong argument for rejecting HPV vaccination in young girls. Not all children are equally at risk for exposure to HPV because transmission requires sexual behavior.<sup>73</sup> For that reason, parents should be able to discuss the issue with health care providers before weighing the need for the vaccine against any potential risks of the

---

<sup>65</sup> The exception to this is the tetanus vaccine. While tetanus is not contagious, exposure is highly likely for children, life threatening, and fully preventable only through vaccination. *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> U.S. CONST. amend. XIV, § 1.

<sup>69</sup> See generally Donald C. Hubin, *Parental Rights and Due Process*, 1 J.L. & FAM. STUD. 123, 123-150 (1999).

<sup>70</sup> *Troxel v. Granville*, 530 U.S. 57 (2000).

<sup>71</sup> *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925).

<sup>72</sup> *Id.*

<sup>73</sup> Javitt et al., *supra* note 50.

vaccination.<sup>74</sup> Research also suggests a general antipathy toward the sort of governmental coercion involved in mandating the HPV vaccine.<sup>75</sup> While many parents may prefer having their daughters vaccinated, fewer might agree that they should be told what to do regarding their child's risk of acquiring HPV.<sup>76</sup>

### 3. Alternative State Responses

The overwhelming majority of states have not mandated the HPV vaccine because of the availability of alternative, less intimidating, measures. Instead of mandating Gardasil by linking it to school entrance, some states have mandated insurance coverage of the vaccine or provided state funding to cover costs for individuals who want the vaccine.<sup>77</sup> Other states have instead focused on educating their adult populations about HPV and Gardasil in an effort to promote educated decision-making regarding the health of their children.<sup>78</sup> Education includes explaining the link between HPV and cervical cancer and the cause of the disease before allowing parents to weigh the risks and benefits for themselves.<sup>79</sup> Finally, some states have established recommendation committees that encourage parents to vaccinate their children for HPV, but do not require it.<sup>80</sup>

---

<sup>74</sup> *Id.*

<sup>75</sup> Colgrove et al., *supra* note 51.

<sup>76</sup> One poll showed that while 61 percent of parents with daughters under 18 prefer vaccination, only 45 percent agreed that the vaccine should be included as part of the vaccination routine for all children and adolescents. *See* Javitt et al., *supra* note 50.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

#### 4. Mandate for Female Immigrants

Despite all the controversy and reservations considered by state legislatures in mandating the HPV vaccine, it was automatically included as a required vaccine for women immigrants.<sup>81</sup> This mandate was a clear violation of international human rights law, especially in relation to discrimination and the creation of an unwitting test population for a new vaccine.<sup>82</sup> The Universal Declaration of Human Rights states in Article 2 that everyone is entitled to all the rights and freedoms set forth by declaration, without distinction of sex and national origin.<sup>83</sup> This would posit that the same rights afforded to U.S. citizens to choose whether or not to take the HPV vaccine would be applicable to an immigrant group.

The International Covenant on Civil and Political Rights, which was ratified by the U.S. in 1992, states the following in Article 7- “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation”.<sup>84</sup> The HPV mandate does not allow female immigrants free consent to make an informed choice about whether or not they would like the vaccine. If one views the mandate as creating a test population to determine any side effects of the vaccine, this would fall squarely in the realm of medical experimentation.<sup>85</sup>

---

<sup>81</sup> Letter from Priscilla Huang, *supra* note 2.

<sup>82</sup> Sheyn, *supra* note 55.

<sup>83</sup> The Universal Declaration of Human Rights is not a ratified treaty, but a formal recognition by all the world’s nations (including the U.S.) “of the rights that we all hold, by virtue of our humanity.” See Alan Jenkins & Sabrineh Ardalan, *Positive Health: The Human Right to Health Care Under the New York State Constitution*, 35 FORDHAM URB. L.J. 479, 514 (2008); *Universal Declaration of Human Rights*, G.A. Res 217A, U.N. GAOR, 3d sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 10, 1948), available at <http://www.un.org/en/documents/udhr/index.shtml>.

<sup>84</sup> International Covenant on Civil and Political Rights, 6 I.L.M. 368, 999 U.N.T.S. 171 (Dec. 16, 1966), available at <http://www2.ohchr.org/english/law/ccpr.htm>; See *FAQ: The Covenant on Civil & Political Rights (ICCPR)*, AM. CIVIL LIBERTIES UNION (Aug. 2012), <http://www.aclu.org/human-rights/faq-covenant-civil-political-rights-iccpr>.

<sup>85</sup> Sheyn, *supra* note 55.

Further, the mandate would not have complied with the limits of domestic police powers and public health articulated in *Jacobson*.<sup>86</sup> First, this immunization requirement was clearly not a public health necessity, else it would be mandated for citizens also. If it is the general public that needs protection, herd immunity only develops if all members of a group undergo preventative treatment.<sup>87</sup> The HPV vaccine could not provide herd immunity, as herd immunity applies only to airborne diseases that spread quickly and easily with no physical contact.<sup>88</sup> Secondly, the requirement was unreasonable. The vaccine placed a harsh monetary burden on female immigrants, as Gardasil was the costliest required vaccine at \$360 for three doses.<sup>89</sup> There is no subsidy for vaccines available to immigrants,<sup>90</sup> and the price could be a barrier to entry. Finally, the mandate was arbitrary and discriminatory. Immigrants are differently situated than American citizens, but there was no evidence that there was a heightened public health threat of HPV from the immigrant population.<sup>91</sup> This would clearly violate the principle set forth in *Williamson* also, as the immigrant population does not demonstrate particular susceptibility to HPV.<sup>92</sup>

Concerns about the safety and efficacy of the vaccine, about forcing children to receive a vaccine for an STI, and about infringing on parental autonomy have all played a role in changing the general opinion regarding a mandate. Immigrant women were not able to consider the safety or efficacy of Gardasil, and immigrant children who were female were forced to get the vaccine.

---

<sup>86</sup> *Jacobson*, *supra* note 11.

<sup>87</sup> *Note: Toward a Twenty-first Century Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1820-1841(2008).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> CDC has established the Federal Vaccines for Children program throughout the U.S. that provides vaccines for children ages 9 to 18 who are covered by Medicaid. *See HPV Vaccine*, NAT'L CONF. OF ST. LEGISLATURES (Nov. 2012), <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx>.

<sup>91</sup> Ching Ping Ang *et al.*, *supra* note 10.

<sup>92</sup> *Williamson*, *supra* note 14.



Further, because HPV is passed by sexual activity, American parents worried that their girls would be labeled as sexually active or promiscuous if they were to get the vaccine.<sup>93</sup> Female immigrants may have been subject to these same public misconceptions, leading to labeling and potential stigma.<sup>94</sup> All of these reasons ignited public outcry over the mandate<sup>95</sup>, and CDC responded in 2009.

### 5. CDC Response and Current Guidelines

In November of 2009, over a year after the vaccination changes, the CDC reported that it would remove both the HPV vaccine and the zoster vaccine from the I-693 health report for immigrants.<sup>96</sup> The mandatory vaccine amendments officially began on December 14, 2009.<sup>97</sup> In addition, the CDC has revised ACIP criteria in regards to which vaccines will be required for U.S. immigrants. The new vaccination criteria include that:

1. The vaccine must be age-appropriate for the immigrant applicant,
2. The vaccine must protect against a disease that has the potential to cause an outbreak, and
3. The vaccine must protect against a disease that has been eliminated or is in the process of being eliminated in the United States.<sup>98</sup>

The new guidelines were promulgated only after the Gardasil vaccine became a prerequisite for residency and naturalization, and only after public criticism of the mandate.<sup>99</sup> But perhaps the

---

<sup>93</sup> Because HPV is transmitted by sexual contact, it implicates “lifestyle choices and behavioral decisions.” See Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 VACCINE 4812, 4815 (2006).

<sup>94</sup> See Erin Kobetz *et al.*, *Perceptions of HPV and Cervical Cancer Among Haitian Immigrant Women: Implications for Vaccine Acceptability*, 24 EDUC. FOR HEALTH 479 (Dec. 2011) (this study found that Haitian immigrant women “felt the HPV vaccine was less appropriate for adolescent girls who are presumed as not sexually active.” Findings like this suggest that HPV vaccine administration is linked to sexual activity in the mind of at least some immigrant groups, which may lead to stigma of vaccinated females depending on how that ethnic group views appropriate sexuality).

<sup>95</sup> Letter from Priscilla Huang, *supra* note 2.

<sup>96</sup> CDC, *supra* note 3.

<sup>97</sup> *Id.*

most troubling issue is the updated guidelines would not have occurred but for this incident, and apparently the vaccine requirement was created by accident in the first place.<sup>100</sup> Jon Abramson, who served as ACIP chair, reported to news media that the panel had not intended for Gardasil to become a required immunization, and that they were not aware that the recommendation would become mandatory for female immigrants.<sup>101</sup> The accidental nature of this mandate underscores the main problem with the updated guidelines- the guidelines were created to address one issue in particular (removing HPV from the required vaccine list for female immigrants), and as such they do nothing to address gender inequity concerns raised by the vaccination requirement.

### III. CRITIQUE AND RECOMMENDATIONS

The most obvious issue with the new ACIP criteria is that it fails to address gender differences, which was in essence the central substantive issue with the immigrant HPV mandate. The new criteria note the importance of age appropriate vaccines for applicants and focus on public health by citing outbreaks and previously eliminated diseases. However, the fact that the HPV vaccine was a requirement for female immigrants only is not solved by these new criteria. The new guidelines fail to consider that another vaccine may be developed that is again specific to one gender. States may refuse to mandate such a vaccine again, but immigrant women could still be forced to receive such a vaccine to complete their applications.

#### *A. Effect of Gender on Vaccine Immunization*

One area of concern for mandating a vaccine by gender is the effect that sex appears to

---

<sup>98</sup> *Id.*

<sup>99</sup> Sheyn, *supra* note 55.

<sup>100</sup> *Id.*

<sup>101</sup> *HPV Vaccine Mandated for Green Card Applicants*, USA TODAY (Oct. 3, 2008), [http://usatoday30.usatoday.com/news/nation/2008-10-02-5042885\\_x.htm?csp=34](http://usatoday30.usatoday.com/news/nation/2008-10-02-5042885_x.htm?csp=34) (Jon Abramson is quoted as saying, "This is an unintended consequence...[w]e didn't even know about the law").

have on the efficacy of immunizations. Research points to clear distinctions in vaccine use and effect between men and women based on biological differences, especially in vaccines for sexually transmitted infections (STIs), like HPV. First, there is evidence of a gender gap in vaccine efficacy. Large phase III clinical studies of one herpes vaccine suggested differences in efficacy between men and women.<sup>102</sup> After Operation Desert Storm in 1997, the U.S. Army vaccinated soldiers against Anthrax.<sup>103</sup> Reports kept by the military show that the response of women to the vaccine differed greatly from the response of males.<sup>104</sup>

There is also evidence of dosage differences between men and women that suggests that women may not need equal dosages.<sup>105</sup> Women's bodies generate a stronger antibody response, and smaller doses for women may decrease more common side effects like pain at the injection site, inflammation and fever.<sup>106</sup> Similar sex differences have been seen in response to vaccines for yellow fever virus, measles, mumps and rubella, and hepatitis A and B viruses.<sup>107</sup>

Vaccine protection may also be distinct in men and women.<sup>108</sup> Because women typically mount stronger immune responses to vaccinations compared to men, injections like the Influenza

---

<sup>102</sup> These are studies for the vaccine HSV-2, completed by GlaxoSmithKline in September 2002. Phase III studies are the last level of studies required by FDA before approval of a drug or biologic (vaccines are a biologic), and are the largest studies of safety and efficacy before the product is available for use in the general public. Researchers found that a vaccine appeared to be 74% efficacious in preventing herpes simplex virus 2 in women, but showed no significant protection in men. See Emily Bass, *Does Gender Matter for HIV Vaccines? New Approaches to an Open Question*, 7 INT'L AIDS VACCINE INITIATIVE (Feb.- Apr. 2003), available at

<http://www.iavireport.org/Back-Issues/Pages/IAVI-Report-07%281%29-DoesGenderMatterforHIVVaccines.aspx>.

<sup>103</sup> *Medical Readiness- Safety and Efficacy of the Anthrax Vaccine*, U.S. GENERAL ACCOUNTING OFFICE, Statement of Kwai-Cheung Chan (Oct. 12, 1999), available at [www.gao.gov/archive/1999/ns99148t.pdf](http://www.gao.gov/archive/1999/ns99148t.pdf).

<sup>104</sup> The difference, at the time, was attributed to women complaining more than men (Bass, *supra* note 102).

<sup>105</sup> See R.J. Engler et al., *Half- vs Full-Dose Trivalent Inactivated Influenza Vaccine- Age, Dose, and Sex Effects on Immune Responses*, 168 ARCHIVES OF INTERNAL MED. 2405, 2405-2414 (Dec. 8, 2008).

<sup>106</sup> Sabra L. Klein. & Phyllis Greenberger, *Do Women Need Such Big Flu Shots?* N.Y. TIMES (Oct. 27, 2009), [http://www.nytimes.com/2009/10/28/opinion/28klein.html?\\_r=2&ref=opinion&](http://www.nytimes.com/2009/10/28/opinion/28klein.html?_r=2&ref=opinion&).

<sup>107</sup> See I.F. Cook, *Sexual Dimorphism of Humoral Immunity with Human Vaccines*, 26 VACCINE 3551, 3551-5 (Jul. 4, 2008).

<sup>108</sup> *Microbiologists and Immunologists Find Women Are Better Protected From Flu Than Men After Vaccination*, AM. INST. OF PHYSICS (2011), <http://www.aip.org/dbis/stories/2010/20141.html>.

virus vaccine might proffer stronger protection in women<sup>109</sup> Further, factors such as vaccine injection time may alter efficacy between sexes.<sup>110</sup> One study has shown that vaccines are more effective when given to men in the morning compared to the afternoon.<sup>111</sup>

Finally, the most salient biological difference between men and women is that of pregnancy, and pregnancy changes vaccine standards for women. There are certain vaccines recommended for all pregnant women, such as influenza and tetanus.<sup>112</sup> However, pregnant women are never given live viruses in order to protect their health and the health of the baby.<sup>113</sup> Pregnancy status dictates what types of vaccines women should or should not receive.

It is impossible to separate gender and immunization effects, which is a critical reason for considering gender before mandating or even recommending certain vaccines. In the case of STIs, the gender differences are all the more salient as diseases have disparate effects on men and women because of reproductive systems. CDC completely missed an opportunity to address gender in the context of immunization law, and this is certainly an issue that will arise again.<sup>114</sup> CDC will once again be in a position where it can only respond once a harm has occurred, which is poor public policy.

---

<sup>109</sup> See Sabra L. Klein, Anne Jedlicka & Andrew Pekosz, *The Xs and Y of Immune Responses to Viral Vaccines*, 10 LANCET INFECTIOUS DISEASES 338, 338-49 (May 2010).

<sup>110</sup> See Anna C. Phillips, *The Vaccination Model in Psychoneuroimmunology Research: A Review*, 934 METHODS IN MOLECULAR BIOLOGY 355, 355-70 (Sep. 5, 2012).

<sup>111</sup> The study also showed that women may benefit more from vaccines received in the afternoon, but the effect seen for women was much smaller than men (*Id.*).

<sup>112</sup> *Vaccines for pregnant women*, NAT'L NETWORK FOR IMMUNIZATION INFO. (Jan. 29, 2009), <http://www.immunizationinfo.org/issues/general/vaccines-pregnant-women>.

<sup>113</sup> Roger W. Harms, *Vaccines During Pregnancy- Are they safe?*, MAYO CLINIC (Dec. 6, 2011), <http://www.mayoclinic.com/health/vaccines-during-pregnancy/AN01886>.

<sup>114</sup> *Vaccines for Sexually Transmitted Diseases*, COLL. OF PHYSICIANS OF PHILA. (2012), <http://www.historyofvaccines.org/content/articles/vaccines-sexually-transmitted-diseases> (explaining that HPV and Hepatitis B vaccines are already in use, and vaccines for genital herpes and HIV are in development and may be successful soon).

### *B. Further Critique*

While the deference of the USCIS to the CDC and in particular, to ACIP as a seat of expertise regarding immunization is intelligible, the direct role of ACIP on immigration policy should be questioned. Specifically, Section 212 of the Immigration and Nationality Act should be amended. As it stands, it requires all immigrants to meet with a doctor and either provide documentation of vaccination for all ACIP recommended vaccines or receive those vaccines from the physician.<sup>115</sup>

There is absolutely no level of review between the ACIP recommendations and the I-693 form,<sup>116</sup> which should be necessary given ACIP's effect on immigration requirements. That lack of review explains how vaccines such as the one for HPV could end up on a mandatory list, though it is a clear violation of law and human rights. The very fact that ACIP recommendations create immigrant requirements was a surprise to ACIP committee members, and this serves as persuasive evidence some intermediate review must be taken between recommendations and mandates.<sup>117</sup>

### *C. Recommendations*

An ideal response would be to remove this relationship altogether, and instead require that immigrants provide proof of age-specific vaccines that are required for all U.S. citizens. For children of school age, this would mean requiring 1) that parents would be well informed about the vaccines their children are to be receiving and 2) that a basic list of required vaccines would be created. The way vaccinations stand currently is that each state has its own immunization

---

<sup>115</sup> *Supra* note 26.

<sup>116</sup> Kimbol, *supra* note 24.

<sup>117</sup> USA TODAY, *supra* note 101.

requirements linked to school attendance for children.<sup>118</sup> In general, those include diphtheria, pertussis, tetanus (lockjaw), *Haemophilus influenzae* type b, measles, mumps, rubella, polio, and hepatitis B.<sup>119</sup> In relation to adults, there are no legally mandated vaccinations for in our country (except for persons entering military service).<sup>120</sup> This is why ACIP was created- to recommend certain immunizations dependent upon age, occupation, and other circumstances- but these immunizations are not required by law.<sup>121</sup>

USCIS should develop its own list of required vaccinations for immigrants based on required vaccinations for all U.S. citizens. Many of the aforementioned vaccines are already on the immigration list, and would simply need to remain there. This list should still be informed by ACIP, but would not mandate any vaccines that are not mandated for current citizens.

This kind of list would address the human rights violations of discrimination and lack of consent, while protecting the population in a means that is not arbitrary. For instance, if American adults do not have to be vaccinated against their will, there is no reason to require that of adult immigrants. While immigrants are not citizens and therefore cannot argue the protection of constitutional rights, the U.S. is party to international human rights treaties.<sup>122</sup> These declarations offer some level of protection for immigrants against arbitrary requirements and harms.<sup>123</sup>

A list ensuring equity between the vaccines that American citizens and immigrants must receive would adequately address gender concerns. This would be a better solution than simply

---

<sup>118</sup> Some states also include varicella to the list of required vaccines (Hodge & Gostin, *supra* note 7).

<sup>119</sup> *Id.*

<sup>120</sup> *National Vaccine Program Office Immunization Laws*, CDC (Dec. 6, 2009), <http://www.hhs.gov/nvpo/law.htm>.

<sup>121</sup> *Id.*

<sup>122</sup> UDHR, *supra* note 83; ICCPR, *supra* note 84.

<sup>123</sup> *Id.*, see *supra* II.C.4.

providing equality among immigrants by requiring the same vaccines for males and females in the naturalization process. Because vaccines can now be distinct by gender, another case like the HPV case could arise under with a vaccine mandate for one sex. Specifically, in the HPV case, the vaccine was not approved for use in males until three years after the use was approved in females.<sup>124</sup> The use of Gardasil in males is completely different than in women, as the vaccine prevents only the outward manifestation of genital warts<sup>125</sup> and males are not at risk for developing cancer of an organ they lack entirely. Gender equity in vaccines for STIs cannot rely on treating males and females the same, but must be brought about by comparing one sex in the American population to the same sex in immigrants.

Furthermore, current CDC guidelines state that health officials can issue recommendations for immunizations in special circumstances.<sup>126</sup> An example is the recommendation for tetanus or typhoid vaccinations in areas that have recently undergone natural disasters.<sup>127</sup> Physicians meeting with immigrants seeking citizenship should recommend certain vaccines that are relevant to the applicant's previous exposures based on country of origin. This is a subjective approach, but also a more accurate and relevant way to address certain diseases than to simply mandate immunizations across the board. With this plan, immigrants are still maintaining the "basic responsibilities of American citizenship" (the CDC spells this out in its current immunization laws) by meeting the immunization standards of all

---

<sup>124</sup> Jonathan D. Rockoff, *Boys' Use Of Gardasil Is Approved*, Wall St. J. (Oct. 17, 2009), available at <http://online.wsj.com/article/SB125572545935790741.html>.

<sup>125</sup> *Id.*

<sup>126</sup> *Supra* note 3.

<sup>127</sup> *Id.*

other Americans, but are concurrently able to maintain a sense of individual rights, which are also valued in our society.<sup>128</sup>

#### *D. Alternative Recommendations*

Assuming that the USCIS seeks to maintain ACIP's control over immunization requirements for immigrants, there is a series of steps that should be taken. The CDC revisions work within the current law without amending it, by setting up stricter guidelines on what the ACIP can recommend.<sup>129</sup> The three new requirements of age appropriate vaccines, vaccines that protect against potential outbreak causing diseases, and diseases that are already eliminated in the U.S.,<sup>130</sup> provide a baseline for determining what vaccines should and should not be mandated for immigrants. Three suggestions would bolster the current situation and take potential gender discrimination into account, without overhauling the hierarchy and deference system that has already been set up in Section 212.

First, CDC should institute an open comment period prior to mandating any recommended vaccines for immigrants. Had this existed earlier, there would have been a consideration of whether or not HPV should be mandated, instead of a backlash from experts and primary organizations in the field.<sup>131</sup> This is a secondary review level, above the newly created recommendation criteria, that would allow room for the nuances of how health, human rights and gender interact in reality. Groups and individuals with experience in certain areas could inform and clarify whether or not a certain vaccine requirement is equitable.

---

<sup>128</sup> A value noted by CDC, *supra* note 120.

<sup>129</sup> Section 212 of the Immigration and Nationality Act, *supra* note 26.

<sup>130</sup> CDC, *supra* note 3.

<sup>131</sup> *Supra* note 33.



Secondly, USCIS must address the current waiver process for immunizations, according to 8 U.S.C. 1182.<sup>132</sup> The law currently states that the Attorney General can waive vaccination requirements if the applicant can 1) provide certification from a civil surgeon, medical officer, or panel physician that a certain vaccination would not be medically appropriate, or 2) prove that religious beliefs or moral convictions are contrary to immunization.<sup>133</sup> So, while waivers can be afforded, they are limited and require the approval of the Attorney General. Those seeking to waive the vaccinations on appropriate grounds are also required to complete form I-601, the Application for Waiver of Ground of Inadmissibility, and submit this form to either the local American Embassy or Consulate, or local USCIS Office.<sup>134</sup> The form has a submission fee of \$545, which is only waived if the applicant has tuberculosis, is mentally disabled, or has a history of mental illness.<sup>135</sup> Clearly, the aims of the requirements are to make the waiver of vaccinations less accessible so as to limit abuse of the system. However, such a high price tag makes the process an impossible consideration for many immigrants, and that is unjust.

The waiver as it currently stands would protect pregnant women applying for U.S. citizenship from inappropriate vaccines. However, the strictness of the waiver means that immigrant women would be unable to make any arguments against a gender specific required vaccine, such as safety or efficacy concerns or personal autonomy. These are the arguments that parents of vaccine-age children can make, yet none of them would be available to immigrants in the current waiver system.

---

<sup>132</sup> *Specifically*: Inadmissible aliens, 8 U.S.C. 1182(a)(1)(A)(ii) (2000).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

Thirdly, from a public health perspective, the focus must further shift from medicalization of disease to prevention. While vaccines can and do serve great purposes in prevention, there are some cases in which they are simply unnecessary. The Gardasil vaccine is a great example of this- while a woman could benefit from getting the vaccine to avoid the potential development of cervical cancer (assuming no other health conditions occur as a direct result of the vaccine), being linked in with an OB-GYN would better address her overall health needs.

Within that context, a simple Pap smear could be used for screening and early detection of cervical cancer. With the bigger picture in mind, immunization requirements that have applicants meet with physicians to receive vaccine administration also work to link patients to primary care physicians for treatment. This may become less complicated as health insurance and coverage expands under the Patient Protection and Affordable Care Act (PPACA).<sup>136</sup>

A change like this creates a basis for overall health improvement, instead of just immunization, which may or may not even be necessary in some cases. It also allows gender-specific concerns to be addressed by appropriate doctors in the context of a physician-patient relationship. Continuous evaluation by a physician is, on its face, a costlier upfront proposition than administering a vaccine. However, the investment in community health has been repeatedly shown to save future costs by addressing potential health problems with treatment before costlier interventions, such as emergency surgery, are required.<sup>137</sup> In fact, the trend of regulation like

---

<sup>136</sup> *Affordable Care Act*, U.S. DEPT. OF LABOR (2012), [http://www.dol.gov/ebsa/healthreform/#.UME\\_i4V1SsM](http://www.dol.gov/ebsa/healthreform/#.UME_i4V1SsM) (The Patient Protection and Affordable Care Act, also known as the Affordable Care Act, is the most significant regulatory reconstruction of American healthcare since the establishment of Medicare and Medicaid in 1965. The statute was signed into law in March 2010 and upheld as constitutional by the U.S. Supreme Court in June 2010).

<sup>137</sup> Glen P. Mays & Sharla A. Smith, *Evidence Links Increases In Public Health Spending To Declines In Preventable Deaths*, 30 Health Aff. 1585, 1585-93 (Jul. 2011).

PPACA is to invest further in public health infrastructure.<sup>138</sup> PPACA will put \$182 million of federal funds into clinical prevention strategies, \$112 million of which will be devoted to access of critical wellness and preventive health services.

#### IV. CONCLUSIONS AND FUTURE RELEVANCE

CDC passed up an opportunity to address gender when the situation seemed just right. The organization had mistakenly mandated a vaccine for female immigrants, and it had to respond with policy changes to quell the agitation of women's groups, health care organizations, organizations for immigrant rights, and human rights groups. Unfortunately, those changes took a short-sighted focus. CDC should revisit these policies before another mistake arises that again leads to unjust and inequitable application of law in the public health context, specifically in regards to gender.

The implementation of any of these recommendations requires cooperation and communication between the USCIS and the CDC. Back and forth communication is what was clearly missing in July of 2008, when the mandatory vaccine list for immigrants was amended with the inclusion of Gardasil. The CDC was correct to reevaluate ACIP policies for vaccine recommendations, especially with relation to the communicability of disease. However, more than just one aspect of this system should be reevaluated to better protect public and immigrant health, male and female alike.

An ideal response would be to require immigrants to show proof of age-specific vaccines that are required for all U.S. citizens. Working only within the current frame of the situation, the

---

<sup>138</sup> *Building Healthier Communities by Investing in Prevention*, U.S. Dept. of Health and Human Serv. (2012), <http://www.healthcare.gov/news/factsheets/2011/02/prevention02092011b.html>.

easiest and quickest thing to institute would be the creation of an open comment period before APIC recommendations become USCIS vaccination requirements. Re-evaluating the reasonableness of current vaccine waiver applications should also be considered, and the completion of I-693 forms should be viewed as a way to introduce patients into primary care. Collectively, these three recommendations would work as checks and balances in a system that has already been shown to be at risk for failing the people it aims to serve.

With relation to the HPV case, as more vaccines are developed for STIs, the ethics around mandating them for immigrants will become increasingly relevant. Vaccines for prostate cancer or HIV will rely on precedent to determine course of action. There are gender differences that affect vaccinations, and sexes must be treated differently in some cases for substantive equality. Future vaccines may be specific to men or women, and the current CDC guidelines have no room to protect each gender. While every vaccine scenario will have its own characteristics, a system that allows for more voices to be heard will result in being the least discriminatory and wisest response.