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# One Step Forward, Two Steps Back: How Mandating the Human Papillomavirus Vaccine Will Increase the Use of Vaccine Exemptions and Negatively Impact Our Nation's Health

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**ONE STEP FORWARD, TWO STEPS BACK:  
HOW MANDATING THE HUMAN  
PAPILLOMAVIRUS VACCINE WILL  
INCREASE THE USE OF VACCINE  
EXEMPTIONS AND NEGATIVELY IMPACT  
OUR NATION'S HEALTH**

*By Katharine Southard\**

INTRODUCTION

A 7-year-old boy went on a family trip to Switzerland in January 2008.<sup>1</sup> Upon arriving back home to San Diego, he caused a measles outbreak in the city.<sup>2</sup> His parents had chosen not to vaccinate him or his siblings,<sup>3</sup> and as a result, he infected at least eleven additional children, ranging in age from ten months to nine years old.<sup>4</sup> All eleven cases were unvaccinated, including eight whose parents had claimed personal belief exemptions.<sup>5</sup>

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\*B.A., Harvard University, 2003; J.D., Brooklyn Law School, expected 2010. The author wishes to thank her husband, Eric, for his encouragement, love and patience. She also wishes to thank her parents for their constant support, love and guidance. Finally, she would like to thank the Journal of Law and Policy for their editorial assistance.

<sup>1</sup> A. Hassidim et al., *Outbreak of Measles—San Diego, California, January-February 2008*, 57 MORBIDITY & MORTALITY WEEKLY REPORT, 203, 203 (2008).

<sup>2</sup> Rong-Gong Lin II & Sandra Poindexter, *California Schools' Risks Rise as Vaccinations Drop*, LOS ANGELES TIMES, Mar. 29, 2009.

<sup>3</sup> *Id.*

<sup>4</sup> Miriam E. Tucker, *San Diego Measles Outbreak Shows the Effect of Vaccine Exemptions*, PEDIATRIC NEWS, Mar. 1, 2008, at 14.

<sup>5</sup> *Id.*

The development of vaccines has greatly improved our nation's health.<sup>6</sup> In order to realize the full benefits of the vaccines, states within the United States have mandated vaccines since the nineteenth century;<sup>7</sup> however, not all children are necessarily subject to these mandates.<sup>8</sup> All fifty states allow for medical exemptions from vaccine requirements, such as a serious allergy to a vaccine component, and most states also allow for religious exemptions.<sup>9</sup> For example, in August 2008, Rita Palma, a mother from Bayport, Long Island, requested that the town's Board of Education allow her son to enter the sixth grade without being immunized, claiming that vaccinations were against her religious beliefs.<sup>10</sup> She stated that "[v]accinations represent fear, anxiety and mistrust in God," and that the idea of vaccinations "contradicts the peace and balance [she] seek[s] in [her] journey to God."<sup>11</sup>

Besides medical and religious exemptions, twenty-one states also grant exemptions for parents who claim philosophical or personal objections to immunization.<sup>12</sup> Some states make these philosophical exemptions easy to obtain, while other states require "notarization, annual renewal, a signature from a local health official, or a personally written letter from a parent."<sup>13</sup> Additionally, many parents of young children are worried that

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<sup>6</sup> See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 376 (2d ed. 2008).

<sup>7</sup> See James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 851 (2002) ("The Commonwealth of Massachusetts incorporated its own school [smallpox] vaccination law in 1855, New York in 1862, Connecticut in 1872, and Pennsylvania in 1895.").

<sup>8</sup> Paul Offit, *Fatal Exemption: Relationship Between Vaccine Exemptions and Rates of Disease*, CENTERS FOR DISEASE CONTROL AND PREVENTION, Jan. 29, 2007, <http://www.cdc.gov/vaccines/vac-gen/laws/fatal-exemption.htm>.

<sup>9</sup> *Id.*; see *infra* note 132 and accompanying text.

<sup>10</sup> Joie Tyrrell, *Taking Another Shot*, NEWSDAY, Aug. 13, 2008, at A08.

<sup>11</sup> *Id.*

<sup>12</sup> Bloomberg News, *More Kids Not Getting Shots*, NEWSDAY, May 7, 2009, at A25.

<sup>13</sup> Offit, *supra* note 8.

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vaccinations may cause autism, and therefore cite this as a personal reason not to vaccinate their child.<sup>14</sup> Many parents, including Erin Micklo from Illinois, believe that the measles, mumps and rubella (“MMR”) vaccination had a negative effect on their children.<sup>15</sup> Micklo recalls that “[w]ithin a couple of days of being vaccinated, the 18-month-old boy developed a high fever and a rash and became extremely lethargic.”<sup>16</sup> Her son was later diagnosed with autism.<sup>17</sup> In the face of frequent parental concern, the Centers for Disease Control (“CDC”) report that “vaccines are not associated with [autism].”<sup>18</sup> Regardless, more parents are opting not to have children vaccinated with all of the shots health officials recommend.<sup>19</sup>

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<sup>14</sup> Neil Osterweil, *US Measles Increase Due to Declining Vaccinations*, MEDSCAPE MEDICAL NEWS, Aug. 28, 2008, <http://www.medscape.com/viewarticle/579800>. Autism is a “severe developmental disorder” that may begin at birth or within the first few years of life. What is Autism?, <http://www.autism.com/autism/index.htm> (last visited Sept. 25, 2009). Most autistic children engage in puzzling behavior that differs from behavior of typical children. *Id.* There is no single best treatment for all children with autism, but research shows that early intervention treatment services can greatly improve a child’s development. Centers for Disease Control and Prevention, Treatment of Autism Spectrum Disorders, <http://www.cdc.gov/ncbddd/autism/treatment.html> (last visited Sept. 25, 2009).

<sup>15</sup> Deborah L. Shelton & Deanes Williams-Harris, *Kids’ Vaccinations Face Risky Resistance Pediatricians Fear That Concerns About Immunization Will Allow Once Vanquished Childhood Diseases to Return*, CHI. TRIB., Aug. 26, 2008, at 1.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> Centers for Disease Control and Prevention, Topics Related to Autism Spectrum Disorders, <http://www.cdc.gov/ncbddd/autism/topics.html> (last visited Sept. 25, 2009) [hereinafter CDC, Topics Related to Autism]. Scientists at Columbia University Mailman School of Public Health’s Center for Infection and Immunity and researchers at the Centers for Disease Control and Prevention, Massachusetts General Hospital, and Trinity College Dublin also conducted a study, which showed no connection between the MMR vaccine and autism. See *Study Firmly Shows No Connection Between Measles, Mumps, Rubella MMR Vaccine and Autism*, HEALTH & MED. WK. 3384 (2008).

<sup>19</sup> Bloomberg News, *supra* note 12.

Due to these parents' decisions to withhold their children from receiving certain vaccinations, the number of unvaccinated children is growing in states that allow parents to exempt their own kids for personal reasons, leading to outbreaks of measles and pertussis (whooping cough).<sup>20</sup> During the first seven months of the year 2008, 131 measles cases in the United States were reported to the CDC.<sup>21</sup> This is the highest level of infection during the same period in any year since 1996.<sup>22</sup> Of those 131 measles cases, 112 victims were either unvaccinated or had no evidence of inoculation.<sup>23</sup> Two thirds of the cases did not receive the measles vaccination for religious or philosophical reasons.<sup>24</sup> With decreasing vaccination rates, two population groups are most susceptible to an epidemic because they are most likely to not be vaccinated: home schooled children and those who hold certain beliefs that do not allow vaccination.<sup>25</sup> Additionally, because measles "is so contagious, [it] is one of the first diseases to reappear when immunization coverage declines."<sup>26</sup> This importance of the MMR vaccine is illustrated by the fact that measles caused approximately 450 annual deaths and 48,000 hospitalizations in the United States before the creation of the measles vaccine in the mid-1960s.<sup>27</sup>

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<sup>20</sup> *Id.*

<sup>21</sup> Editorial, *Measles Returns*, N.Y. TIMES, Aug. 24, 2008, at WK8.

<sup>22</sup> *Id.*

<sup>23</sup> Osterweil, *supra* note 14.

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

<sup>25</sup> *US Measles Increase Caused by Vacc Scare*, PHARMA MARKETLETTER, Sept. 1, 2008.

<sup>26</sup> Editorial, *supra* note 21.

<sup>27</sup> Osterweil, *supra* note 14. Common symptoms of measles include rash, fever, cough, and runny nose. Centers for Disease Control and Prevention, Overview of Measles, <http://www.cdc.gov/measles/about/overview/html> (last visited Sept. 25, 2009). However, approximately 20% of those infected report more serious complications including ear infections (one out of every 10 children), pneumonia (one out of 20 children), and encephalitis (one out of every 1,000 children). *Id.* Encephalitis is an inflammation of the brain that can lead to convulsions and can cause a child to become deaf or mentally retarded. Centers for Disease Control and Prevention, Complications of Measles, <http://www.cdc.gov/measles/about/>

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Similarly, whooping cough cases have also increased recently.<sup>28</sup> A recent study suggests that children are twenty-three times more likely to get whooping cough if they are not vaccinated against the disease.<sup>29</sup> The co-authors of the study state that, “[t]he results dispel vaccine-refusing parents’ belief ‘that their children are not at risk for preventable diseases.’”<sup>30</sup>

Measles and whooping cough are just two of the many diseases that children are vaccinated against.<sup>31</sup> In recent years, the number of mandated vaccinations has increased so that children now may get as many as thirty-three inoculations to prevent fifteen diseases.<sup>32</sup> A new vaccine has recently been added to that list.<sup>33</sup> In June 2006, the Food and Drug Administration (FDA) announced the approval of Gardasil®, “the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human

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complications.html (last visited Sept. 25, 2009). Further, for every 1,000 children who get measles, one or two will die from it. *Id.* “Measles also can make a pregnant woman have a miscarriage, give birth prematurely, or have a low-birth-weight baby.” *Id.*

<sup>28</sup> *Study: Pertussis Shots Work*, NEWSDAY, May 26, 2009, at A29. “In 2007, 10,454 cases were reported nationwide, including 10 children who died.” *Id.*

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

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

<sup>31</sup> See ANDREW T. KROGER ET AL., CTNS. FOR DISEASE CONTROL AND PREVENTION, GENERAL RECOMMENDATIONS ON IMMUNIZATION: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES 3 (2006). The Advisory Committee on Immunization Practices (ACIP) “develops written recommendations for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration number of doses and dosing interval, and precautions and contraindications.” Centers for Disease Control and Prevention, Vaccines: ACIP, <http://www.cdc.gov/vaccines/recs/acip/default.htm> (last visited Sept. 25, 2009) [hereinafter CDC, Advisory Committee on Immunization Practices].

<sup>32</sup> Bloomberg News, *supra* note 12.

<sup>33</sup> See Press Release, Food and Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm>.

papillomavirus (HPV) types 6, 11, 16 and 18.”<sup>34</sup> During the following year, in 2007, “at least 24 states and D.C. introduced legislation to specifically mandate the HPV vaccine for school.”<sup>35</sup> Among these twenty-four states, only Virginia and D.C. have moved toward requiring sixth-grade girls to receive the vaccination.<sup>36</sup> Both Virginia and D.C. passed laws in 2007, but “pushed back their start dates to [2009] to allow more study of the vaccine.”<sup>37</sup>

Although the HPV vaccine may reduce the incidence of HPV and cervical cancer, there is great debate over mandating the vaccine.<sup>38</sup> Parents and guardians object to the HPV vaccine for different reasons than those who object to vaccines such as the MMR vaccine.<sup>39</sup> While some opponents of mandatory HPV vaccination for school admission maintain that mandatory vaccination preempts parental authority to make health decisions for one’s child, or that the safety of the vaccine is still in doubt, others morally object to required vaccines for a sexually transmitted disease.<sup>40</sup> According to the first national survey

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

<sup>35</sup> National Conference of State Legislatures, HPV Vaccine, <http://www.ncsl.org/IssuesResearch/Health/HPVVaccineStateLegislation> (last visited Sept. 25, 2009) [hereinafter NCSL, HPV Vaccine].

<sup>36</sup> Dena Potter, *HPV Vaccine a Suggestion, Not Mandate in DC, VA*, NEWSDAY, Sept. 1, 2009, at A35.

<sup>37</sup> *Id.* The Virginia legislature passed a school vaccine requirement in 2007, and considered a bill that would delay that requirement, but the Senate Committee declined to take action on the bill. NCSL, HPV Vaccine, *supra* note 35; S. 722, 2008 Session (Va. 2008).

<sup>38</sup> See, e.g., Cheryl A. Vamos et al., *The HPV Vaccine: Framing the Arguments FOR and AGAINST Mandatory Vaccination of All Middle School Girls*, 78 J. SCH. HEALTH 302 (2008); Linda Marsa, *Gardasil’s Chorus of Doubters*, L.A. TIMES, Aug. 11, 2008, at 1.

<sup>39</sup> See generally Amanda Gardner, *Many Moms Unwilling to Have Younger Daughters Get HPV Vaccine*, HEALTH DAY (May 5, 2008) (finding that parents are likely to object to vaccination because of doubts of its effectiveness to prevent cervical cancer and because they believed it would cause the child to engage in riskier sexual behavior).

<sup>40</sup> Rachel Meisterman, Note, *The Aftermath of the Introduction of the Human Papillomavirus Vaccination*, 3 J. HEALTH & BIOMEDICAL L. 313, 331

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measuring attitudes towards the HPV vaccine since its FDA approval in 2006, “only half of American mothers intend to have their teenaged daughters vaccinated against human papillomavirus (HPV) if the girls are under the age of 13, despite government guidelines that suggest the opposite.”<sup>41</sup> Further, “[u]nlike other diseases for which state legislatures have mandated vaccination for children, HPV is neither transmissible through casual contact nor potentially fatal during childhood.”<sup>42</sup>

Because of the differences between the HPV vaccination and vaccinations that prevent airborne diseases, the District of Columbia and Virginia—who have passed legislation requiring the HPV vaccination for females—have included broad opt-out provisions in their statutes.<sup>43</sup> The District of Columbia’s legislation allows the parent or legal guardian to opt out “for any reason.”<sup>44</sup> Similarly, Virginia’s legislation allows parents or guardians to refuse the HPV vaccination for their daughter “after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.”<sup>45</sup> Because of the current resistance by parents to vaccinate their daughters at a young age,<sup>46</sup> many parents will likely exercise their right to opt-out.

This Note argues that the ease of which a parent can decide against vaccinating their child with the HPV vaccine may then

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(2007).

<sup>41</sup> Gardner, *supra* note 39. The CDC currently recommends the vaccine for all eleven and twelve-year-old girls, and for females aged thirteen through twenty-six years old who have not been previously vaccinated or who have not completed the full series of shots. Centers for Disease Control and Prevention, HPV Vaccine-Questions & Answers for the Public, <http://www.cdc.gov/vaccines/vpd-vac/hpv/hpv-vacsafe-ffic.htm> (last visited Oct. 18, 2009) [hereinafter CDC, Questions & Answers for the Public].

<sup>42</sup> Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 384 (2008).

<sup>43</sup> See VA. CODE ANN. § 32.1-46(D) (West 2008); see also D.C. CODE § 7-1651.04(b)(1)(B)(iii)(2001).

<sup>44</sup> D.C. CODE § 7-1651.04(b)(1)(B)(iii).

<sup>45</sup> VA. CODE ANN. § 32.1-46 (D)(3).

<sup>46</sup> See Gardner, *supra* note 39.



encourage parents to seek exemptions for other vaccines, thus causing re-emergence of diseases like measles and whooping cough. Partly due to parents' concerns that vaccines are linked to rising rates of autism, more parents are opting not to have their children vaccinated.<sup>47</sup> Giving parents the option to decline the HPV vaccine with such ease may provide additional encouragement for parents to decline other vaccinations for their children as well. Including such broad opt-out provisions in state statutes, as the District of Columbia and Virginia have done, may ultimately result in a disastrous return of childhood diseases.

Part I of this Note provides background information on HPV and its link to cervical cancer, as well as information on the HPV vaccine, Gardasil®. Part II examines the foundational case of *Jacobson v. Massachusetts*<sup>48</sup> and the current use of exemptions in the anti-vaccination movement. Part III discusses the actions taken thus far by state legislatures regarding the HPV vaccine and the various objections to mandating the HPV vaccine for school entry. Part III further concludes that mandating the HPV vaccine with broad opt-out provisions could encourage parents and guardians to then seek exemptions to other previously mandated vaccines which protect against diseases that *are* communicable in a school setting. Finally, Part IV concludes that although the approval of a vaccine against cancer-causing HPV strains is a tremendous development, mandating the HPV vaccine for school entry while including broad opt-out provisions may actually undermine our nation's health.

## I. BACKGROUND

### A. *Human Papillomavirus Virus*

Each year 6.2 million people become infected with human papillomavirus (HPV), the most common sexually transmitted

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<sup>47</sup> Bloomberg News, *supra* note 12.

<sup>48</sup> 197 U.S. 11 (1905).

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infection.<sup>49</sup> Seventy-four percent of those infected are between the ages of fifteen and twenty-four.<sup>50</sup> This is in addition to the approximately twenty million Americans who are already infected.<sup>51</sup> Over fifty percent of sexually active men and women acquire genital HPV at some point throughout their lives,<sup>52</sup> and women have an eighty percent chance of getting HPV by the time they are fifty years of age.<sup>53</sup>

At least thirty of the more than 100 types of HPV can be passed from one person to another through sexual contact.<sup>54</sup> Since most HPV infections are asymptomatic,<sup>55</sup> many people are unaware when they have become infected with HPV.<sup>56</sup> As a result, most infected individuals do not realize that they are passing the virus to a partner since the virus may be transmitted even when it's asymptomatic.<sup>57</sup> In ninety percent of cases, "the body's immune system clears the HPV infection naturally within two years;"<sup>58</sup> however, some cases of HPV infection persist for many years and may cause cell abnormalities, increasing a woman's risk of developing cervical cancer.<sup>59</sup>

HPV types can be classified into two types: "low-risk" and

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<sup>49</sup> Centers for Disease Control and Prevention, Genital HPV Infection, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last visited Oct. 24, 2009) [hereinafter CDC, Genital HPV].

<sup>50</sup> LAURI E. MARKOWITZ ET AL., CTRS. FOR DISEASE CONTROL AND PREVENTION, QUADRIVALENT HUMAN PAPILLOMAVIRUS VACCINE 4 (2007).

<sup>51</sup> CDC, Genital HPV, *supra* note 49.

<sup>52</sup> *Id.*

<sup>53</sup> CDC, Questions & Answers for the Public, *supra* note 41.

<sup>54</sup> National Cancer Institute, Human Papillomavirus and Cancer, <http://www.cancer.gov/cancertopics/factsheet/Risk/HPV/> (last visited Oct. 24, 2009) [hereinafter NCI, HPV and Cancer]. Although the surest way to avoid risk of developing HPV is to refrain from sexual contact, a study among newly sexually active college women demonstrated a 70 percent reduction in HPV infection when their partners used condoms. MARKOWITZ ET AL., *supra* note 50, at 7.

<sup>55</sup> NCI, HPV and Cancer, *supra* note 54.

<sup>56</sup> CDC, Genital HPV, *supra* note 49.

<sup>57</sup> *Id.*

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

<sup>59</sup> NCI, HPV and Cancer, *supra* note 54.

“high-risk,” depending on whether or not they cause lesions that develop into cancer.<sup>60</sup> “Both high-risk and low-risk types of HPV can cause the growth of abnormal cells, but only the high-risk types [such as types sixteen and eighteen] of HPV lead to cancer.”<sup>61</sup> The American Cancer Society estimates that in 2009, 11,270 women will be diagnosed with cervical cancer, and approximately 4,070 women will die from cervical cancer in the United States.<sup>62</sup>

Still, the incidence of cervical cancer in the United States is very low compared with other parts of the world.<sup>63</sup> Each year, eighty-five percent of the roughly 473,000 cervical cancer cases worldwide afflict women in developing countries.<sup>64</sup> Of those 473,000 cases, an estimated 253,500 lead to deaths.<sup>65</sup> In many developing countries, cervical cancer is the greatest cause of cancer-related deaths among women,<sup>66</sup> primarily because developing countries lack the screening and treatment programs that exist in the United States.<sup>67</sup>

### B. Gardasil® Vaccine

In 2006, the FDA approved Merck & Co.’s Gardasil®, a vaccine for females that is effective in preventing infection with HPV types six, eleven, sixteen, and eighteen.<sup>68</sup> The vaccine does

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<sup>60</sup> *Id.*

<sup>61</sup> *Id.* “These high-risk types of HPV cause growths on the cervix that are usually flat and nearly invisible, as compared with the external warts caused by low-risk types HPV-6 and HPV-11.” *Id.*

<sup>62</sup> American Cancer Society, Detailed Guide: Cervical Cancer, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1X\\_What\\_are\\_the\\_key\\_statistics\\_for\\_cervical\\_cancer\\_8.asp?rnav=cri](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_cervical_cancer_8.asp?rnav=cri) (last visited Sept. 25, 2009).

<sup>63</sup> See National Cervical Cancer Coalition, <http://www.nccc-online.org> (last visited Sept. 25, 2009).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

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

<sup>67</sup> Javitt et al., *supra* note 42, at 385.

<sup>68</sup> U.S. FOOD AND DRUG ADMIN., GARDASIL PACKAGE INSERT (2009) [hereinafter GARDASIL PACKAGE INSERT]. GlaxoSmithKline is awaiting FDA

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not protect against all strains of HPV, but HPV types sixteen and eighteen are responsible for about seventy percent of cervical cancer cases worldwide.<sup>69</sup> The CDC currently recommends the vaccine for all eleven- and twelve-year-old girls, and for females aged thirteen through twenty-six years old “who have not been previously vaccinated or who have not completed the full series of shots.”<sup>70</sup> The vaccine consists of three injections, during a six-month period, and may be given at the same time as other vaccines.<sup>71</sup> While the CDC claims that the HPV vaccine does not appear to cause any major side effects,<sup>72</sup> there were 15,037 reports of adverse events following Gardasil® vaccination made to the CDC’s Vaccine Adverse Event Reporting System (VAERS) as of September 1, 2009.<sup>73</sup> Of these, ninety-three percent were classified as reports of non-serious events,<sup>74</sup> and seven percent as serious events.<sup>75</sup> Common complaints include pain, redness or swelling at the injection site.<sup>76</sup> However, there have been 44 U.S. reports of death among

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approval on its vaccine, Cervarix. NCSL, HPV Vaccine, *supra* note 35.

<sup>69</sup> NCI, HPV and Cancer, *supra* note 54. The other two HPV types targeted by the vaccine—HPV-6 and HPV-11—cause approximately ninety percent of the cases of genital warts. *Id.*

<sup>70</sup> Ctrs. for Disease Control and Prevention, HPV Vaccine- Questions & Answers, <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm> (last visited Oct. 18, 2009). The recommendation “allows for vaccination to begin at age nine” and the CDC stresses that the “vaccine is most effective for girls/women who get vaccinated before their first sexual contact.” *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> Press Release, Ctrs. for Disease Control and Prevention, HPV Vaccine: What You Need to Know (Feb. 2, 2007), *available at* <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv.pdf>.

<sup>73</sup> Centers for Disease Control and Prevention, Reports of Health Concerns Following HPV Vaccination, <http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm> (last visited Oct. 24, 2009) [hereinafter CDC, Health Concerns Following Vaccination]. As of September 1, 2009, more than 26 million doses of Gardasil were distributed in the United States. *Id.*

<sup>74</sup> *Id.* Non-serious adverse events have included fainting, arm pain and swelling at the injection site, headache, nausea and fever. *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* Eight out of ten individuals complain of pain at the injection site and one out of four individuals complain of redness or swelling at the

females who have received the vaccine.<sup>77</sup> Still, of the 27 reports of death that have been confirmed, there was nothing to suggest that they were caused by the vaccine.<sup>78</sup>

Guillain-Barré Syndrome (GBS), a rare neurological disorder that causes muscle weakness, has also been reported in individuals following vaccination with Gardasil®.<sup>79</sup> There were 36 reported cases of GBS by girls after HPV vaccination in the U.S. from 2006 to 2008.<sup>80</sup> In seventy-five percent of those cases, the disorder occurred within six weeks after receiving the vaccination.<sup>81</sup> However, the CDC reports that there is no evidence that Gardasil® has increased the rate of GBS above that expected in the population,<sup>82</sup> but “the fact that most of [the] cases occurred within six weeks of vaccination does warrant careful monitoring for any additional cases and continued analysis.”<sup>83</sup> Further, while thromboembolic disorders (blood clots) have been reported to VAERS, most of these individuals had risk factors for blood clots, such as use of oral contraceptives, which are known to increase the risk of clotting.<sup>84</sup>

However, one known side effect associated with the HPV vaccine, fainting, caused the FDA to require that vaccine manufacturer Merck & Co. add a warning to the vaccine’s package insert.<sup>85</sup> The warning now recommends that patients be

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injection site. *Id.*

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

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

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

<sup>80</sup> *Researchers: Guillain-Barre Syndrome After HPV Vaccine Needs Monitoring*, OBESITY, FITNESS & WELLNESS WK. 3272 (2009) [hereinafter *Monitoring of Guillain-Barre Syndrome*]. As of September 1, 2009, more than 26 million doses of Gardasil were distributed in the United States. CDC, Health Concerns Following Vaccination, *supra* note 73.

<sup>81</sup> *Id.*

<sup>82</sup> CDC, Health Concerns Following Vaccination, *supra* note 73. GBS “occurs in 1–2 out of every 100,000 people in their teens.” *Id.*

<sup>83</sup> *Monitoring of Guillain-Barre Syndrome*, *supra* note 80.

<sup>84</sup> CDC, Health Concerns Following Vaccination, *supra* note 73.

<sup>85</sup> Steven Reinberg, *25% of Teen Girls Vaccinated for HPV*, HEALTH

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observed “for 15 minutes after administration” of the vaccine.<sup>86</sup> The CDC and the FDA plan to continue to monitor the safety of Gardasil® as is customary with approved vaccines.<sup>87</sup>

II. HISTORY OF VACCINATION AND SCHOOL VACCINATION REQUIREMENTS

*A. The Foundations of Public Health Law and Mandatory Immunizations: Jacobson v. Massachusetts*<sup>88</sup>

The Tenth Amendment of the U.S. Constitution states: “the powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”<sup>89</sup> These powers include a state’s “police powers” which “relate to the safety, health, morals and general welfare of the public.”<sup>90</sup> While protecting the public’s health, a state “is limited by individual rights to autonomy, privacy, liberty, property, and other legally protected interests.”<sup>91</sup> Balancing an individual’s constitutional rights with the duty of the state to protect the public’s health “poses an enduring problem for public health law.”<sup>92</sup>

Vaccination programs are a “core component” of public health in the United States, supported by state legal requirements, federal funding and oversight.<sup>93</sup> Each state has school vaccination laws mandating vaccination of children for certain diseases.<sup>94</sup> Communicable diseases, for which there are

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DAY, Oct. 9, 2008.

<sup>86</sup> GARDASIL PACKAGE INSERT, *supra* note 68.

<sup>87</sup> CDC, Health Concerns Following Vaccination, *supra* note 73.

<sup>88</sup> 197 U.S. 11 (1905).

<sup>89</sup> U.S. CONST. amend. X.

<sup>90</sup> *Lochner v. New York*, 198 U.S. 45, 53 (1905).

<sup>91</sup> GOSTIN, *supra* note 6, at 11.

<sup>92</sup> *Id.*

<sup>93</sup> Hodge & Gostin, *supra* note 7, at 833.

<sup>94</sup> See CTRS. FOR DISEASE CONTROL AND PREVENTION, CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, 2005–2006 (2006), *available at* <http://www.cdc.gov/vaccines/vac-gen/laws/downloads/izlaws05-06.pdf>

vaccines, have dramatically decreased since the introduction of school vaccination laws.<sup>95</sup>

Mandatory immunization laws in the United States first appeared in the early nineteenth century<sup>96</sup> in an effort to combat outbreaks of smallpox.<sup>97</sup> In 1827, Boston became the first city to require vaccination for all children entering public schools<sup>98</sup> and by the late nineteenth century, the trend toward compulsory child vaccination as a condition of school attendance spread to the midwestern and western states.<sup>99</sup>

In 1905, the U.S. Supreme Court made what is “widely regarded as the seminal decision in American public health law”<sup>100</sup> in *Jacobson v. Massachusetts*,<sup>101</sup> and set the standard for state mandatory vaccination laws.<sup>102</sup> Proceeding under the statutes of Massachusetts, the Board of Health of Cambridge adopted a regulation mandating the smallpox vaccination for “all the inhabitants of Cambridge” in February 1902.<sup>103</sup> Jacobson, who refused the vaccination, argued that “a compulsory vaccination law is unreasonable, arbitrary, and oppressive, and therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best. . . .”<sup>104</sup> However, the Court did not rule in Jacobson’s

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[hereinafter CDC, SCHOOL IMMUNIZATION REQUIREMENTS].

<sup>95</sup> Hodge & Gostin, *supra* note 7, at 834.

<sup>96</sup> *Id.* at 849.

<sup>97</sup> *Id.* at 850. Smallpox is a “serious, contagious, and sometimes fatal infectious disease.” Centers for Disease Control and Prevention, Smallpox Disease Overview, <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp> (last visited Sept. 25, 2009). Unlike HPV, smallpox can be transmitted through the air. *Id.* Generally, direct and prolonged face-to-face contact is necessary to spread smallpox from one individual to another; however, smallpox has also been spread through the air in enclosed settings. *Id.*

<sup>98</sup> Hodge & Gostin, *supra* note 7, at 851.

<sup>99</sup> *Id.*

<sup>100</sup> KENNETH WING ET AL., PUBLIC HEALTH LAW 59 (2007).

<sup>101</sup> 197 U.S. 11 (1905).

<sup>102</sup> See WING ET AL., *supra* note 100, at 59.

<sup>103</sup> *Jacobson*, 197 U.S. at 12.

<sup>104</sup> *Id.* at 26.

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favor and decided that “[t]he safety and health of the people of [the state] are, in the first instance, for [the state] to guard and protect.”<sup>105</sup> The *Jacobson* case “upholds the constitutional validity of the state’s curtailment of individual liberty in the interests of public health.”<sup>106</sup>

Notably, the Supreme Court in *Jacobson* recognized the limits of a state’s power and imposed certain criteria that must be met when requiring vaccinations.<sup>107</sup> First, there must be a public health necessity.<sup>108</sup> The state cannot exercise its power in “an arbitrary, unreasonable manner”<sup>109</sup> and may not go “beyond what was reasonably required for the safety of the public.”<sup>110</sup> Second, there must be a reasonable relationship between the intervention and the objective.<sup>111</sup> The methods employed by the state must have a “real or substantial relation to the protection of the public health and the public safety”<sup>112</sup> and cannot be “a plain, palpable invasion of rights secured by the fundamental law.”<sup>113</sup> Third, the law cannot be “wholly disproportionate to the expected benefit.”<sup>114</sup> The state may not use its police powers to create regulations that are “arbitrary and oppressive.”<sup>115</sup> Fourth, the law may not require that an adult who is not “a fit subject of

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<sup>105</sup> *Id.* at 38.

<sup>106</sup> WING ET AL., *supra* note 100, at 59.

<sup>107</sup> *Id.* at 62.

<sup>108</sup> *Jacobson*, 197 U.S. at 28. The court in *In re Christine M.*, a 1992 New York case, declined to require inoculation of the child against smallpox due to the fact that “the urgency previously created by the [measles] epidemic or outbreak” had decreased. *In re Christine M.*, 595 N.Y.S.2d 606, 618 (N.Y. Fam. Ct. 1992).

<sup>109</sup> *Jacobson*, 197 U.S. at 28.

<sup>110</sup> *Id.*

<sup>111</sup> *See id.* at 28; *see also* GOSTIN, *supra* note 6, at 127 (analyzing the approach of the *Jacobson* Court in its adoption of the means/ends test which necessitates “a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective.”).

<sup>112</sup> *Jacobson*, 197 U.S. at 31.

<sup>113</sup> *Id.*

<sup>114</sup> GOSTIN, *supra* note 6, at 127.

<sup>115</sup> *Jacobson*, 197 U.S. at 38.



vaccination” get vaccinated.<sup>116</sup> Requiring vaccination that would impair one’s health “would be cruel and inhuman in the last degree.”<sup>117</sup> Finally, although “[t]he facts in *Jacobson* did not require the Supreme Court to enunciate a standard of fairness under the Equal Protection Clause of the Fourteenth Amendment[,]”<sup>118</sup> the federal courts had already developed a standard of fairness in an earlier case, *Jew Ho v. Williamson*.<sup>119</sup> Therefore, “while *Jacobson* stands firmly for the proposition that police powers authorize states to compel vaccination for the public good,”<sup>120</sup> the state may only require its inhabitants to be vaccinated when it was “necessary for the public health or the public safety.”<sup>121</sup>

Although there have been many objections to mandatory vaccinations, “[t]he early successes of school vaccination laws against most political, legal, and social challenges helped lay the foundation for modern immunization statutes.”<sup>122</sup> Since the introduction of smallpox vaccination laws, statutes have continuously added new vaccines to the mandatory school vaccination lists.<sup>123</sup> The criteria set forward in *Jacobson* provide

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<sup>116</sup> *Id.* at 39.

<sup>117</sup> *Id.* at 38–39.

<sup>118</sup> GOSTIN, *supra* note 6, at 128.

<sup>119</sup> *Id.* In *Jew Ho v. Williamson*, 103 F. 10 (N.D. Cal. 1900), the court struck down a quarantine that was made to operate exclusively against the Chinese community in San Francisco. *Id.* at 26. In striking down the quarantine, the federal district court said it was “unreasonable, unjust, and oppressive, . . . and . . . it [was] discriminating in its character. . . .” *Id.*

<sup>120</sup> Hodge & Gostin, *supra* note 7, at 857.

<sup>121</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905).

<sup>122</sup> Hodge & Gostin, *supra* note 7, at 867.

<sup>123</sup> Although state laws differ, most states require immunizations such as: Diphtheria, Tetanus, and acellular Pertussis (DTaP), Hepatitis A, Hepatitis B, Haemophilus influenzae Type b, Measles, Mumps, and Rubella (MMR), and Polio for school age children. See CDC, SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 94. In October 2008, New Jersey became the first state to mandate flu shots for children from 6 months to 5 years old who attend day care or preschool. Ridgely Ochs, *NJ Flu Shot Mandate Sparks Protest*, NEWSDAY, Oct. 17, 2008, at A2. This requirement resulted in various protests and “freedom of choice rall[ies]” by parents and other

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the guidelines for the introduction of these new vaccination laws.<sup>124</sup>

*B. The Recent Debate Concerning School Vaccination Requirements and the Use of Exemptions*

CDC officials estimate that “over time [the country’s vaccination] program has prevented about 14 million cases of vaccine-preventable diseases and 33,000 premature deaths.”<sup>125</sup> Incidences of vaccine-preventable disease are near historical lows.<sup>126</sup> Childhood illnesses for which there are now vaccines, such as measles, pertussis, mumps, rubella, diphtheria, tetanus and polio, “once accounted for a substantial proportion of child morbidity and mortality.”<sup>127</sup> Yet, since the development of vaccines, the incidence of these illnesses has “significantly declined.”<sup>128</sup> However, although most infants are vaccinated, many under-immunized children remain, potentially causing disease outbreaks.<sup>129</sup>

Parents and guardians who object to vaccinating their children often take advantage of vaccination law exemptions.<sup>130</sup> These exemptions have been growing at a “disturbing” rate.<sup>131</sup>

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activists. *Id.*

<sup>124</sup> See WING ET AL., *supra* note 100, at 59.

<sup>125</sup> Centers for Disease Control and Prevention, Press Briefing Transcripts, <http://www.cdc.gov/media/transcripts/2008/t080905.htm> (last visited Sept. 25, 2009).

<sup>126</sup> Centers for Disease Control and Prevention, Vaccines & Immunizations, <http://www.cdc.gov/vaccines/default.htm> (last visited Sept. 30, 2009).

<sup>127</sup> Hodge & Gostin, *supra* note 7, at 875.

<sup>128</sup> *Id.*

<sup>129</sup> Centers for Disease Control and Prevention, Vaccines & Preventable Diseases, <http://www.cdc.gov/vaccines/vpd-vac/default.htm> (last visited Sept. 30, 2009).

<sup>130</sup> Jennifer Steinhauer & Gardiner Harris, *Rising Public Health Risk Seen As More Parents Reject Vaccines*, N.Y. TIMES, Mar. 21, 2008, at A1.

<sup>131</sup> *Id.* For example, in California, more than 10,000 kindergartners started school in fall 2008 with vaccine exemptions, up from about 8,300 in fall 2007. Lin & Poindexter, *supra* note 2. “In 1997, when enrollment was

All fifty states have medical exemptions to vaccine requirements, and forty-eight states have religious exemptions.<sup>132</sup> In addition, twenty-one states allow parents to exempt their children for personal reasons, sometimes related to an unproven concern that vaccines are linked to autism.<sup>133</sup> According to Saad B. Omer, an assistant scientist at the Johns Hopkins Bloomberg School of Public Health, “[i]n 1991, less than 1 percent of children in the states with personal-belief exemptions went without vaccines based on the exemption; by 2004, the most recent year for which data are available, the percentage had increased to 2.54 percent.”<sup>134</sup> Dr. Omer and other vaccine experts have discovered that “the easier it is to get an exemption . . . the more people opt for them.”<sup>135</sup>

There are also differences in immunization coverage within states.<sup>136</sup> As a result of the use of exemptions, “[t]here tend to be geographic clusters of ‘exempters’ in certain counties or even neighborhoods or schools.”<sup>137</sup> This may cause individuals who are part of an unvaccinated cluster to infect a broad community,

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higher, the number of exempted kindergartners was 4,318.” *Id.*

<sup>132</sup> Offit, *supra* note 8. Although state requirements vary for what is necessary to prove a medical or religious exemption, Virginia’s statute grants a medical exemption if “[t]he parent or guardian presents a statement from a physician licensed to practice medicine in Virginia, or a licensed nurse practitioner, that states that the physical condition of the child is such that the administration of one of more of the required immunizing agents would be detrimental to the health of the child.” VA. CODE ANN. § 32.1-46(D)(2) (West 2008). A religious exemption may be granted in Virginia if “[t]he parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices, unless an emergency or epidemic of disease has been declared by the Board.” *Id.* at § 32.1-46(D)(1).

<sup>133</sup> See Bloomberg News, *supra* note 12.

<sup>134</sup> Steinhauer & Harris, *supra* note 130, at A1.

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

<sup>136</sup> *Id.*

<sup>137</sup> *Id.* “[E]xemption rates of 15 percent to 18 percent have been found in Ashland, Ore[gon], and Vashon, Wash[ington]. In California, where the statewide rate is about 1.5 percent, some counties were as high as 10 percent to 19 percent of kindergartners.” *Id.*

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which includes people who have been inoculated.<sup>138</sup>

The increased use of philosophical objections to mandatory vaccine statutes is largely due to concerns that vaccinations are linked to autism.<sup>139</sup> Even though “[t]he American Academy of Pediatrics, the CDC, the World Health Organization and the Institute of Medicine all agree that there’s probably no relationship between autism and vaccines,”<sup>140</sup> concern among parents remains.<sup>141</sup>

The suspicion that there exists a link between vaccines and autism is partly due to the fact that parents are “bombarded with” information on the Internet, “making it tough to separate good science from bad.”<sup>142</sup> This information can frequently “take

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<sup>138</sup> *Id.*

<sup>139</sup> See Alice Park, *How Safe Are Vaccines?*, TIME, June 2, 2008, at 36. Although the autism issue has been driving the debate over vaccine safety, parents also object to the mandatory nature of the shots and the fact that certain illnesses, which kids are being inoculated against, are rarely seen anymore. *Id.* There tend to be two separate issues concerning vaccines and autism. Martin F. Downs, *Autism-Vaccine Link: Evidence Doesn't Dispel Doubts*, WEBMD, Mar. 31, 2008, <http://www.webmd.com/brain/autism/searching-for-answers/vaccines-autism>. One issue arises from objections to the MMR vaccine, and the other issue is regarding thimerosal, “which contains a form of mercury that has been suspected of causing autism and has recently been removed from most vaccines.” *Id.*

<sup>140</sup> *Id.* In February 2009, a panel of court-appointed experts “denied compensation for three families who claimed thimerosal-containing vaccine combinations caused their children’s autism.” Christina Hernandez & Delthia Ricks, *Vaccine-Autism Link Not Seen*, NEWSDAY, Feb. 13, 2009, at A08. These three “test” cases are among more than 4,800 families nationwide who are part of the Omnibus Autism Proceedings before the U.S. Court of Federal Claims in Washington D.C. *Id.* The experts found that the families failed to demonstrate that “thimerosal-containing vaccines can contribute to causing immune dysfunction, or that the MMR vaccine can contribute to causing [autism].” *Id.*

<sup>141</sup> See *supra* text accompanying note 19.

<sup>142</sup> Downs, *supra* note 139. The battle over vaccine safety has also been present in the tabloids and on television. Lin & Poindexter, *supra* note 2. Actress Jenny McCarthy, whose son was diagnosed as autistic, “has been outspoken in her beliefs that children are given too many vaccines too soon.” *Id.*

a life of its own online.”<sup>143</sup> Some parents who have withheld vaccinations from their children said they did so after hearing about possible side-effects in the media, online and through other parents.<sup>144</sup> Lee Sanders, MD, MPH, associate professor of pediatrics at the University of Miami Miller School of Medicine, explains that “[i]n the absence of any answers from the scientific community, any scintilla of suggestion is going to get magnified by the social process of talking it out.”<sup>145</sup> Further, in May 2008, the U.S. government acknowledged that a 9-year-old Georgia girl with a preexisting cellular disease received inoculations when she was an infant, which “significantly aggravated” the condition, resulting in a brain disorder with autism-like symptoms.<sup>146</sup> Even though the CDC states that there is likely no relationship between vaccines and autism,<sup>147</sup> confused parents continue to opt out of vaccines altogether.<sup>148</sup>

Still, autism concerns are not the only reason parents are increasingly opting out of vaccinations for their children. Parents “object to the mandatory nature of the shots—and the fact that their child’s access to education hinges on compliance with the immunization regulations.”<sup>149</sup> In addition, others consider certain “tame” diseases to be innocuous “rite[s] of passage” for children.<sup>150</sup> Individuals may also “overestimate the frequency of rare risks,” such as adverse events following vaccination, or “underestimate the frequency of common risks,” such as the

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<sup>143</sup> Downs, *supra* note 139.

<sup>144</sup> Lin & Poindexter, *supra* note 2.

<sup>145</sup> Downs, *supra* note 139.

<sup>146</sup> Park, *supra* note 139.

<sup>147</sup> CDC, Topics Related to Autism, *supra* note 18.

<sup>148</sup> Park, *supra* note 139.

<sup>149</sup> *Id.*

<sup>150</sup> Sean Coletti, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1359 (2004). To illustrate, some parents purposefully expose their children to chicken pox: “[s]ome parents even have ‘chicken pox parties’—when one child comes down with the chicken pox, parents from all over the neighborhood bring their children to catch the disease and start the immunity process ‘naturally.’” *Id.*

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devastating effects of disease.<sup>151</sup> This distortion may be due to the fact that while one can easily remember recent adverse reactions to vaccinations, it is difficult to remember adverse effects of diseases, such as smallpox and polio, that were largely eliminated decades ago.<sup>152</sup> Regardless of the reasons behind the increased use of philosophical exemptions, this trend could cause disease outbreaks.<sup>153</sup>

### III. HPV VACCINATION

#### *A. State Legislative Activities*

The Advisory Committee on Immunization Practices (“ACIP”), whose members provide advice on the control of vaccine-preventable diseases,<sup>154</sup> began to recommend the HPV vaccination for girls between the ages eleven and twelve in June 2006.<sup>155</sup> This recommendation created a flood of state legislative activity regarding whether or not vaccinations should be required for these girls.<sup>156</sup>

Michigan was the first state to introduce legislation in September 2006, requiring the HPV vaccine for girls entering sixth grade.<sup>157</sup> The bill, however, was not enacted.<sup>158</sup> Similarly, Ohio’s legislation in late 2006 requiring the vaccine also failed due to the controversial nature of the vaccine.<sup>159</sup> As of September 2009, “[l]egislators in at least 41 states and D.C. have introduced legislation to require, fund or educate the public

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<sup>151</sup> *Id.* at 1369.

<sup>152</sup> *Id.*

<sup>153</sup> See CDC, Vaccines & Preventable Diseases, *supra* note 129.

<sup>154</sup> CDC, Advisory Committee on Immunization Practices, *supra* note 31.

<sup>155</sup> MARKOWITZ ET AL., *supra* note 50, at 16.

<sup>156</sup> See NCSL, HPV Vaccine, *supra* note 35. Although most state legislatures decide the issues related to school vaccination requirements, some state legislatures have granted regulatory bodies such as the Health Department the power to require vaccines. *Id.*

<sup>157</sup> NCSL, HPV Vaccine, *supra* note 35.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

about the HPV Vaccine and at least 19 states have enacted this legislation.”<sup>160</sup>

Iowa and Illinois, for example, have passed legislation regarding public HPV education.<sup>161</sup> Iowa’s education standards require that the health curriculum for grades seven through twelve “shall include age-appropriate and research-based information regarding the characteristics of sexually transmitted diseases, including HPV and the availability of a vaccine to prevent HPV.”<sup>162</sup> In Illinois, the Communicable Disease Prevention Act requires that “the Department of Health must provide all female students who are entering the sixth grade and their parents or legal guardians written information about the link between human papillomavirus (HPV) and cervical cancer and the availability of a HPV vaccine.”<sup>163</sup> Illinois has also introduced legislation requiring funding of the vaccine: “the Department of Public Health shall establish and administer a program, commencing no later than July 1, 2011, under which any eligible individual shall, upon the eligible individual’s request, receive a series of HPV vaccinations as medically indicated, at no cost to the eligible individual.”<sup>164</sup>

Even more controversial than the legislation passed to fund or educate the public about the HPV vaccine is the fact that at least twenty-four states and the District of Columbia introduced legislation to specifically mandate the HPV vaccine for school in 2007.<sup>165</sup> Among these twenty-four states, only Virginia and D.C. have moved toward required vaccinations for sixth-grade girls.<sup>166</sup> Both Virginia and D.C. passed laws in 2007, but “pushed back their start dates to [2009] to allow more study of the vaccine.”<sup>167</sup>

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<sup>160</sup> *Id.*

<sup>161</sup> See IOWA CODE § 256.11 (2008); see also 410 ILL. COMP. STAT. 315/2e(a) (2008).

<sup>162</sup> IOWA CODE § 256.11.

<sup>163</sup> 410 ILL. COMP. STAT. 315/2e(a).

<sup>164</sup> 20 ILL. COMP. STAT. 2310/2310–617(b) (2008).

<sup>165</sup> NCSL, HPV Vaccine, *supra* note 35.

<sup>166</sup> Potter, *supra* note 36.

<sup>167</sup> *Id.* The Virginia legislature passed a school vaccine requirement in 2007, and considered a bill that would delay that requirement, but the Senate

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In April 2007, Virginia passed a law requiring the HPV vaccine for females where the first dose must be administered before the child entered the sixth grade.<sup>168</sup> The act lists the HPV vaccination requirement directly after the previously mandated vaccines in the state, including the tetanus toxoid, measles, mumps, rubella and polio vaccines.<sup>169</sup> However, the law makes a special exception for the HPV vaccine:

[b]ecause the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.<sup>170</sup>

Thus, parents or guardians are not required to vaccinate their child against HPV so long as they read the relevant materials.<sup>171</sup>

The District of Columbia also enacted a bill mandating HPV vaccination for female sixth-graders within the District.<sup>172</sup> This requirement took effect at the start of the 2009 school year.<sup>173</sup> Similar to the exemptions offered for the other mandatory vaccines, the statute offers both a medical exemption and a religious exemption to the HPV vaccination requirement.<sup>174</sup> However, due to the vast differences between the HPV vaccination and previously mandated vaccines, the law allows

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Committee declined to take action on the bill. NCSL, HPV Vaccine, *supra* note 35; S. 722, 2008 Session (Va. 2008).

<sup>168</sup> VA. CODE ANN. § 32.1-46(A)(12) (West 2008).

<sup>169</sup> *See id.* at § 32.1-46(A).

<sup>170</sup> *Id.* at § 32.1-46(D)(3).

<sup>171</sup> *See id.* Female students are asked to bring in documentation if they got the vaccine. Potter, *supra* note 36. If they do not bring documentation, officials assume parents chose not to get the vaccination. *Id.*

<sup>172</sup> D.C. CODE § 7-1651.04(b)(1) (2001).

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at § 7-1651.04(b)(1)(B)(i)-(ii); *see also* National Vaccine Information Center, State Vaccine Requirements, <http://www.nvic.org/Vaccine-Laws/state-vaccine-requirements.aspx> (last visited Sept. 25, 2009).



for an extremely broad opt-out provision.<sup>175</sup> The statute states that a child is exempted from the HPV vaccine requirement if “[t]he parent or legal guardian, in his or her discretion, has elected to opt out of the HPV vaccination program, for any reason, by signing a form . . . that states the parent or legal guardian has been informed of the HPV vaccination requirement and has elected not to participate.”<sup>176</sup> In addition to the broad opt-out option, the statute “[r]equires all communications from the Department of Health on the HPV vaccination program to prominently feature information pertaining to the ability of parents or guardians to opt out of the program.”<sup>177</sup> This, combined with the mere requirement of signing a form, indicates a strong effort to advertise the voluntary nature of the HPV vaccination. Thus, although both Virginia and D.C. now require HPV vaccinations for sixth-grade girls, the broad opt-out provisions make the vaccine “more of a suggestion than a mandate.”<sup>178</sup>

### *B. Objections to Mandating the HPV Vaccine*

#### *1. The HPV Vaccine Differs from Traditional Infectious Disease Vaccines*

Since *Jacobson*, courts have continued to rule that states can mandate vaccination of their citizens.<sup>179</sup> Yet, in these cases, the vaccine was used to combat an airborne disease, such as

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<sup>175</sup> See D.C. CODE § 7-1651.04(b)(1)(B)(iii).

<sup>176</sup> *Id.* If the female students haven’t either gotten the shot or turned in a form saying their parents opted out, the “girls will be held out of classes.” Potter, *supra* note 36.

<sup>177</sup> D.C. CODE § 7-1651.04(a)(2).

<sup>178</sup> Potter, *supra* note 36.

<sup>179</sup> In *Zucht v. King*, the United States Supreme Court upheld a local mandate for vaccination as a prerequisite for public school attendance. *Zucht v. King*, 260 U.S. 174, 176–77 (1922). State supreme courts have also upheld school vaccination requirements. See, e.g., *People ex rel. Hill v. Bd. of Educ.*, 195 N.W. 95, 99 (Mich. 1923).

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smallpox.<sup>180</sup> HPV is different from other types of diseases which mandatory vaccines are designed to protect. Joseph Zanga, a professor of pediatrics, summed it up as follows:

If a kid with measles is sitting in a classroom, he or she is going to infect many other classmates. A kid with HPV infects no one other than one she might have sex with . . . We're not protecting the public health in the same way that we protect public health when we require measles vaccine.<sup>181</sup>

With mandatory vaccinations, the state's interest is "in protecting the public against diseases that frequently occur in school-based epidemics or threaten school attendance when an epidemic manifests. . . ."<sup>182</sup> The HPV vaccine, on the other hand, is a sexually-transmitted disease that will not spread in a conventional school setting.<sup>183</sup>

*2. The Vaccine Does Not Protect Against All  
Types of HPV That Cause Cancer*

In the United States, cervical cancer screening has reduced the number of cervical cancer cases.<sup>184</sup> Even with the introduction of the HPV vaccination, cervical cancer screening will still be necessary because the vaccine does not protect

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<sup>180</sup> See, e.g., *Hill*, 195 N.W. at 99. While "[t]he driving force behind compulsory vaccination laws was a series of outbreaks of smallpox," the existence of "measles in schools in the 1960s and 1970s" prompted modern immunization statutes. GOSTIN, *supra* note 6, at 379.

<sup>181</sup> Susan Levine & Hamil R. Harris, *Wave of Support for HPV Vaccination of Girls; D.C., Md., Va. Proposals Part of National Effort to Prevent Cervical Cancer*, WASH. POST, Jan. 12, 2007, at B01.

<sup>182</sup> Lane Wood, *A Young Vaccine For Young Girls: Should the Human Papillomavirus Vaccination Be Mandatory For Public School Attendance?*, 20 NO. 5 HEALTH LAW. 30, 33 (2008).

<sup>183</sup> See CDC, *Genital HPV*, *supra* note 49.

<sup>184</sup> American Cancer Society, *supra* note 62. Mostly due to the increased use of the Pap test, the cervical cancer death rate declined by seventy-four percent between 1955 and 1992. *Id.* "The death rate from cervical cancer continues to decline by nearly 4% a year." *Id.*

against all types of HPV that cause cancer.<sup>185</sup> In addition, women who are vaccinated will still need cervical cancer screening because some women may not get all required doses of the vaccine, and because women may have already acquired a vaccine HPV type, preventing them from obtaining the vaccine's full benefits.<sup>186</sup> Indeed, some doctors and parents worry that blanket immunizations could create a false sense of security causing women to neglect regular screening,<sup>187</sup> which might actually raise cervical cancer rates.<sup>188</sup> Further, "even doctors who helped devise the vaccine point out that Pap screening may be more effective in cutting cervical cancer rates."<sup>189</sup> These doctors note that vaccinating every single twelve-year-old "should reduce by half the number of cervical cancers in the next 35 years," whereas Pap screening would reduce the incidence of cervical cancer by nearly seventy-five percent.<sup>190</sup> Thus, given the existence of the screening measures already available, mandating the HPV vaccination is an unnecessary step.

### 3. HPV Is Sexually Transmitted

The HPV vaccine is different from most other vaccines, in that it protects against a disease which is sexually transmitted.<sup>191</sup> Thus, one concern is that required vaccinations will promote premarital sex and risky sexual behavior.<sup>192</sup> Janet Gilsdorf, Director of Pediatric Infectious Diseases and Immunology at the University of Michigan C.S. Mott Children's Hospital, says that

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<sup>185</sup> MARKOWITZ ET AL., *supra* note 50, at 17. The vaccine protects against four types of HPV, including two that cause about 70% of cervical cancer. *Id.*

<sup>186</sup> CDC, Questions & Answers for the Public, *supra* note 41.

<sup>187</sup> Marsa, *supra* note 38.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* (quoting Dr. Diane Harper, Director of the Gynecological Cancer Prevention Research Group at Dartmouth Medical School in Hanover, N.H.).

<sup>191</sup> See CDC, Genital HPV, *supra* note 49.

<sup>192</sup> Vamos et al., *supra* note 38.

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“[t]he reality is, many children get shots and they don’t ask what they’re for.”<sup>193</sup> Therefore, the HPV vaccination does not need to result in “a major parent-child discussion about sex.”<sup>194</sup> Yet, another view is that this lack of openness may be inconsistent with the goal of preventing HPV and cervical cancer and that education is a key to preventing the disease.<sup>195</sup> In addition, not only do parents worry that requiring the HPV vaccine for adolescent girls will encourage sexual behavior, but also that mandating the vaccine infringes “on the decision-making powers of parents . . . regarding what is acceptable medical and sexual behavior.”<sup>196</sup>

*4. The HPV Vaccine Is Still New—Studies  
Are Inconclusive*

Others object to the vaccine’s mandatory use because “there are too many unknowns.”<sup>197</sup> During testing, only 1184 of the 25,000 patients in the clinical trial were preteen girls,<sup>198</sup> the age group that is targeted in proposed, as well as approved, legislation.<sup>199</sup> The co-founder of the National Vaccine Information Center remarked that “that’s a thin base of testing upon which to make a vaccine mandatory.”<sup>200</sup> Further, it is not yet known how long the immunity will last, or whether eliminating some strains of cancer-causing virus will decrease

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<sup>193</sup> Levine & Harris, *supra* note 181.

<sup>194</sup> *Id.*

<sup>195</sup> See CDC, Genital HPV, *supra* note 49.

<sup>196</sup> Vamos et al., *supra* note 38, at 304.

<sup>197</sup> *Id.* See, e.g., Marsa, *supra* note 38 (Sandra Levy has “serious reservations” about having her eleven-year-old daughter inoculated with the HPV vaccine since “we really don’t know if it’s 100% safe.”).

<sup>198</sup> Vamos et al., *supra* note 38, at 305.

<sup>199</sup> Virginia’s statute requires that “[t]he first dose shall be administered before the child enters the sixth grade.” VA. CODE ANN. § 32.1-46(a)(12) (West 2008). Similarly, the District of Columbia’s statute requires parents of females “enrolling in grade 6 for the first time” to submit vaccination certification. D.C. CODE § 7-1651.04(b)(1) (2008).

<sup>200</sup> Vamos et al., *supra* note 38, at 305.

the body's natural immunity to other strains of the virus.<sup>201</sup>

In addition, although there have not been many serious adverse reactions to the vaccine,<sup>202</sup> it is likely that "all possible side effects of the vaccine have not been determined."<sup>203</sup> Moreover, the known adverse effects such as Guillain-Barré Syndrome (GBS) and blood clots are "a sobering reminder that rare adverse events may surface as the vaccine is administered to millions of girls and young women."<sup>204</sup> Because of these medical unknowns, "Gardasil's side effects have made some pediatricians more reluctant to recommend it for their youngest patients."<sup>205</sup> As one research associate at Judicial Watch stated, "It's hard to say right now how effective [the vaccination] is. Making it mandatory is using the U.S. as a public health experiment."<sup>206</sup>

#### 5. *The Consequences of HPV Are Not Sufficient To Mandate Vaccination for School Entry*

Although the states are advised by the CDC regarding which vaccines should be required, "states should mandate vaccines primarily for diseases that are highly contagious, cause significant morbidity and mortality, and pose a major health threat to students, teachers, or the community."<sup>207</sup> Many of the previously mandated vaccinations were required in order to protect children from devastating diseases.<sup>208</sup> For example,

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<sup>201</sup> Elisabeth Rosenthal, *Researchers Question Wide Use of HPV Vaccine*, N.Y. TIMES, Aug. 20, 2008, <http://www.nytimes.com/2008/08/21/health/21vaccine.html>.

<sup>202</sup> See *supra* Part I.B.

<sup>203</sup> Vamos et al., *supra* note 38, at 305.

<sup>204</sup> Javitt et al., *supra* note 42, at 387.

<sup>205</sup> Susan Todd, *Merck Pressing for OK to Market Gardasil for Males*, THE STAR-LEDGER, Jan. 12, 2009.

<sup>206</sup> Victoria Stagg Elliott, *HPV Vaccine Talk Shifts From Fanfare to Fear*, AM. MED. NEWS, Sept. 15, 2008.

<sup>207</sup> GOSTIN, *supra* note 6, at 380.

<sup>208</sup> See Centers for Disease Control and Prevention, *What Would Happen If We Stopped Vaccinations?*, <http://www.cdc.gov/vaccines/vac-gen/>

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before the polio vaccine was available, 13,000 to 20,000 cases of paralytic polio were reported annually in the United States leaving children “in braces, crutches, wheelchairs, and iron lungs.”<sup>209</sup> In the years before the Hib meningitis vaccine was available, the disease killed 600 children per year and left many survivors with deafness, seizures, or mental retardation.<sup>210</sup> Diphtheria was a major cause of illness and death for children in the U.S. before a diphtheria vaccine was created.<sup>211</sup> In addition, from 1964 through 1965, before the rubella immunization was routinely used, an epidemic of rubella resulted in an estimated 20,000 infants born with congenital rubella syndrome, of which 11,600 were deaf, 3,580 were blind and 1,800 were mentally retarded.<sup>212</sup>

Unlike these diseases, HPV-induced cervical cancer is a slow process that generally takes many years, and, therefore, does not affect children.<sup>213</sup> Further, most of the time, HPV goes away on its own,<sup>214</sup> and “few women who have HPV get cervical cancer.”<sup>215</sup> Thus, many of the reasons that justified mandating previous vaccinations do not exist with respect to the HPV vaccination.<sup>216</sup>

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whatifstop.htm (last visited Sept. 25, 2009).

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> See Centers for Disease Control and Prevention, Common Questions About HPV and Cancer, <http://www.cdc.gov/STD/HPV/common-questions.htm> (last visited Sept. 25, 2009) [hereinafter CDC, Common Questions].

<sup>214</sup> CDC, Genital HPV, *supra* note 49.

<sup>215</sup> CDC, Common Questions, *supra* note 213. “Studies suggest that whether a woman develops cervical cancer depends on a variety of factors acting together with high-risk HPVs. The factors that may increase the risk of cervical cancer in women with HPV infection include smoking and having many children.” NCI, HPV and Cancer, *supra* note 54.

<sup>216</sup> See GOSTIN, *supra* note 6, at 380.

6. Mandating the HPV Vaccine  
Is Inconsistent with *Jacobson*

Unlike previously mandated vaccinations, requiring the HPV vaccination would not fit within the principles articulated in *Jacobson*.<sup>217</sup> First, since HPV is passed on through sexual contact,<sup>218</sup> it cannot be transmitted in a classroom setting from student to student.<sup>219</sup> Therefore, unlike the smallpox vaccine in *Jacobson*, the HPV vaccine is not “necessary for the public health or the public safety.”<sup>220</sup> The decision to mandate vaccination in *Jacobson* occurred “in the midst of a smallpox epidemic when there was no other less coercive means available to staunch the outbreak. . . . vaccination was a medical necessity to combat the disease.”<sup>221</sup> Conversely, mandating the HPV vaccination is not a public health necessity because individuals can protect themselves through disease screening, safe sex and abstinence.<sup>222</sup>

Although like HPV, hepatitis B is passed on through sexual contact, and tetanus cannot be transmitted in a classroom setting, these diseases differ from HPV in that they still fall within the “public health necessity” category.<sup>223</sup> For example, although hepatitis B may be transmitted sexually, it may also be communicated in other manners.<sup>224</sup> Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected.<sup>225</sup> People can become infected with the virus while sharing needles,

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<sup>217</sup> See *supra* Part II.A.1.

<sup>218</sup> CDC, Genital HPV, *supra* note 49.

<sup>219</sup> *Id.*

<sup>220</sup> See *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>221</sup> Note, *Toward a Twenty-First-Century*, 121 HARV. L. REV. 1820, 1820 (2008).

<sup>222</sup> *Id.*

<sup>223</sup> See *Jacobson*, 127 U.S. at 28.

<sup>224</sup> Centers for Disease Control and Prevention, Hepatitis B FAQs for the Public, <http://www.cdc.gov/hepatitis/B/bFAQ.htm> (last visited Sept. 25, 2009).

<sup>225</sup> *Id.*

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syringes, or other drug-injection equipment, sharing items such as razors or toothbrushes with an infected person, or by direct contact with the blood or open sores of an infected person.<sup>226</sup> In 2002, an Arkansas district court upheld the decision by the Arkansas legislature that required all children entering daycare, elementary and middle schools to receive the hepatitis B vaccine.<sup>227</sup> While comparing the situation to *Jacobson*, the court stated:

Hepatitis B may not be airborne like smallpox; however, this is not the only factor by which a disease could be judged dangerous. Hepatitis B is spread by bodily fluids; the virus is ‘fairly [hearty] and can survive on surfaces, door knobs, et cetera, for up to a month.’ . . . Immunization of school children against Hepatitis B has a real and substantial relation to the protection of the public health and the public safety. The Court therefore finds that requiring schoolchildren to be immunized against Hepatitis B is a reasonable exercise of the State’s police power and is constitutionally permissible.<sup>228</sup>

Further, although tetanus is not contagious, it is not necessarily preventable. “[G]iven [children’s] propensity to both play in the dirt and get scratches,”<sup>229</sup> tetanus may easily be obtained in a school setting. Unlike many parents’ reaction to the HPV vaccine, parents are “very accepting of the Tetanus vaccine,”<sup>230</sup> both because the disease is not necessarily always preventable and “because of the clear and obvious danger that their child may step barefooted on a nail or do some other dangerous activity.”<sup>231</sup> HPV, on the other hand, is preventable—by refraining from sexual activity.<sup>232</sup>

Second, mandating the HPV vaccination does not fit within

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<sup>226</sup> *Id.*

<sup>227</sup> *Boone v. Boozman*, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002).

<sup>228</sup> *Id.*

<sup>229</sup> *Javitt et al.*, *supra* note 42, at 389.

<sup>230</sup> *Coletti*, *supra* note 150, at 1368.

<sup>231</sup> *Id.*

<sup>232</sup> CDC, Genital HPV, *supra* note 49.



the *Jacobson* principle that there must be a “reasonable relationship between the public health intervention and the achievement of a legitimate public health objective.”<sup>233</sup> Previously mandated vaccinations meet the “reasonable relationship” requirement because school-aged children are most at risk of contracting infectious diseases while in school.<sup>234</sup> Moreover, “[a]ll children who attend school are equally at risk of both transmitting and contracting the diseases.”<sup>235</sup> On the other hand, since HPV is sexually transmitted, exposure to the disease is not directly related to attending school.<sup>236</sup> In addition, not all children are at equal risk of getting HPV since “[t]hose who abstain from sexual conduct are not at risk for transmitting or contracting HPV.”<sup>237</sup> Further, arguably it is not “reasonable” to mandate the HPV vaccine at this point given the limited amount of testing.<sup>238</sup>

Third, requiring the HPV vaccine for adolescent females could be considered “disproportionate to the expected benefit.”<sup>239</sup> This is not only due to the relatively low incidence of cervical cancer in the United States compared with the rest of the world,<sup>240</sup> but also because the HPV vaccine only protects against four of the strains of HPV.<sup>241</sup> Further, since the “overall prevalence of HPV types associated with cervical cancer is relatively low (3.4%),”<sup>242</sup> mandating the vaccine for all girls may be viewed as “disproportionate.”<sup>243</sup>

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<sup>233</sup> GOSTIN, *supra* note 6, at 127.

<sup>234</sup> Javitt et al., *supra* note 42, at 389.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> See *supra* Part III.B.4.

<sup>239</sup> GOSTIN, *supra* note 6, at 127.

<sup>240</sup> See National Cervical Cancer Coalition, <http://www.nccc-online.org/> (last visited Sept. 25, 2009).

<sup>241</sup> NCI, HPV and Cancer, *supra* note 54.

<sup>242</sup> Lawrence O. Gostin & Catherine D. DeAngelis, *Mandatory HPV Vaccination: Public Health vs. Private Wealth*, 297 JAMA 1921, 1921 (2007).

<sup>243</sup> See GOSTIN, *supra* note 6, at 127.

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Finally, mandating the HPV vaccine may not withstand a fairness analysis under the Equal Protection Clause since it is currently only administered to females.<sup>244</sup> Under the heightened scrutiny that is required for laws making sex-based distinctions, the state would have to “justify its decision to burden females with the risks of vaccination, and not males, even though males also contribute to HPV transmission.”<sup>245</sup> In October 2009, the Food and Drug Administration approved the use of Gardasil in boys and men ages nine to twenty-six to protect them from genital warts; however, the ACIP did not encourage “its routine use in boys, as it has recommended for girls.”<sup>246</sup> The group “questioned whether vaccinating boys was a cost-effective way to protect their future sexual partners against cervical and other types of cancer caused by . . . HPV.”<sup>247</sup>

*C. The Possible Effects of Mandatory HPV Vaccination Laws*

Many parents and guardians are currently choosing to take advantage of exemptions to prevent their child from receiving certain vaccinations.<sup>248</sup> Due to the availability of exemptions, “nearly one-half of 1% of kids enrolled in school are unvaccinated under a medical waiver; 2% to 3% have a nonmedical one, and the numbers appear to be rising.”<sup>249</sup> Additionally, in an effort to avoid potential conflicts,<sup>250</sup> some

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<sup>244</sup> See GARDASIL PACKAGE INSERT, *supra* note 68.

<sup>245</sup> Javitt et al., *supra* note 42, at 392.

<sup>246</sup> Natasha Singer, *Vaccine Against Virus in Girls May Be Given to Boys*, N.Y. TIMES, Oct. 22, 2009, at A25.

<sup>247</sup> *Id.* Although males cannot contract cervical cancer, they can become infected with HPV and transmit the virus to others. Centers for Disease Control and Prevention, HPV and Men Fact Sheet, <http://www.cdc.gov/STD/HPV/STDFact-HPV-and-men.htm> (last visited Sept. 25, 2009). Most men who get HPV do not develop any symptoms; however, it can cause health problems, such as genital warts, anal or penile cancer. *Id.*

<sup>248</sup> See Park, *supra* note 139.

<sup>249</sup> *Id.*

<sup>250</sup> Health officials are beginning “to take a harder line with parents who submit vaccine exemptions for nonmedical reasons.” *Id.* In November 2007,

parents are choosing to “homeschool their kids so they won’t be forced to vaccinate them” with certain vaccines, such as the MMR vaccine.<sup>251</sup>

If states follow Virginia’s or D.C.’s lead and mandate the HPV vaccine for girls entering the sixth grade, it is likely that even *more* parents will opt out of the HPV vaccine for their children.<sup>252</sup> Parents and guardians will object to the HPV vaccine for all of the same reasons that they object to vaccines in general, such as concerns regarding autism and the mandatory nature of the shots.<sup>253</sup> However, due to the nature of HPV and the HPV vaccine, the vaccine presents additional worries.<sup>254</sup> Since the HPV vaccine is not a public health necessity in the same way that other mandated vaccines are,<sup>255</sup> “[i]t is this qualitative difference between the HPV vaccine and more traditional vaccines that resonated with the public and with state lawmakers in seeking broad exemptions to mandatory vaccination.”<sup>256</sup>

Virginia’s statute allows parents to choose not to have their daughter vaccinated as long as they review “materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.”<sup>257</sup> This makes it relatively simple for parents to opt out of vaccinating their child.<sup>258</sup>

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officials in Maryland “threatened to take parents to court for truancy violations if their kids did not get all their shots.” *Id.* On Long Island, parents are called in for “‘sincerity’ interviews with school officials . . . to determine how genuinely the vaccines conflict with religious convictions.” *Id.*

<sup>251</sup> *Id.*

<sup>252</sup> See *supra* text accompanying note 41. There is also a risk of “parental rejection of the vaccine because it is perceived as coercive.” Javitt et al., *supra* note 42, at 390.

<sup>253</sup> Park, *supra* note 139.

<sup>254</sup> See *supra* Part III.B.

<sup>255</sup> Note, *Toward a Twenty-First-Century*, *supra* note 221, at 1838.

<sup>256</sup> *Id.* at 1839.

<sup>257</sup> VA. CODE ANN. § 32.1-46(D)(3) (West 2008).

<sup>258</sup> The Virginia statute also allows for medical exemptions if [t]he parent or guardian presents a statement from a physician licensed to practice medicine in Virginia, or a licensed nurse practitioner, that states that the physical condition of the child is such

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Although the statute differentiates the HPV vaccine by stating that it “is not communicable in a school setting,”<sup>259</sup> the ease in which a parent can exercise this opt out right could encourage parents to then seek exemptions to other previously mandated vaccines which protect against diseases that *are* communicable in a school setting.

The HPV vaccine is dissimilar to previously mandated vaccines,<sup>260</sup> which is why it is expected to draw additional scrutiny by parents.<sup>261</sup> Further, the ability to opt out of the HPV vaccine is not masked. In fact, the District of Columbia’s legislation specifically calls for the advertisement of the opt-out provision of the HPV vaccination: all “communications from the Department of Health on the HPV vaccination program” must “prominently feature information pertaining to the ability of parents or guardians to opt out of the program.”<sup>262</sup> Thus, many parents will likely exercise their right to opt-out of the HPV vaccination for their daughters.<sup>263</sup>

The broad opt-out provision for the HPV vaccine may bring some parents and guardians, who otherwise might not have, to look into the availability of vaccine exemptions in their state for other vaccines. Although parents would likely use the philosophical exemption if it is available in their state, “more and more parents today are claiming religious exemptions regardless of whether the religion they belong to explicitly prohibits it.”<sup>264</sup> Further, in states without philosophical

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that the administration of one or more of the required immunizing agents would be detrimental to the health of the child and for religious exemptions if “[t]he parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices.” *Id.* at § 32.1-46(D)(1)-(2).

<sup>259</sup> *Id.* at § 32.1-46(D)(3).

<sup>260</sup> See *supra* Part III.B.1.

<sup>261</sup> See Gardner, *supra* note 39; see also Marsa, *supra* note 38.

<sup>262</sup> D.C. CODE § 7-1651.04 (2008).

<sup>263</sup> See Gardner, *supra* note 39.

<sup>264</sup> Coletti, *supra* note 150, at 1350. For example, in New Jersey, to file for a religious exemption, a parent only needs to “write a letter stating how the vaccines conflict with the family’s religious beliefs.” Jill P. Capuzzo,

exemptions, besides using religious or medical exemptions, parents may also send their children to parochial or private schools or home school their children, increasing alternatives for parents seeking to avoid vaccinating their children.<sup>265</sup> In sum, introducing parents to the idea of opting out of the HPV vaccination for their daughter may encourage these parents to seek exemptions not only for the HPV vaccine, but for other previously mandated vaccines that have proved to be tremendously effective over the years. Once parents realize the ease of which they can opt out of the HPV vaccine, they may then seek to opt out of other vaccines by using exemptions. The increased use of exemptions is already a cause for concern, primarily due to recent measles and whooping cough outbreaks,<sup>266</sup> and any additional encouragement to opt out of mandatory vaccines will only exacerbate the situation.

#### IV. CONCLUSION

From 2007 to 2008, the number of thirteen to seventeen-year-old girls who had received the first of three doses of the HPV vaccine increased from 25 to 37 percent.<sup>267</sup> This increase occurred, despite the fact that most states have not instituted a HPV vaccine requirement for school entry.<sup>268</sup> Therefore, this

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*Some Parents Seek Options to Vaccine Orders*, N.Y. TIMES, Dec. 23, 2007. Verification by a member of the clergy is not required. *Id.* Further, organizations exist to assist parents in their application. *See id.* For example, Barbara Flynn, a mother of two, has a Web site, [www.callingtheshots.info](http://www.callingtheshots.info), where she provides a sample three-page letter that parents can use when drafting their own letter. *Id.*

<sup>265</sup> Capuzzo, *supra* note 264.

<sup>266</sup> *See* Bloomberg News, *supra* note 12.

<sup>267</sup> David Olmos, *Third of Teen Girls Get Cancer Vaccine*, NEWSDAY, Sept. 18, 2009, at A32. Rates of vaccination “varied widely among the states, from 54.4 percent in New Hampshire to 15.8 percent in Mississippi.” *Id.*

<sup>268</sup> *See* NCSL, HPV Vaccine, *supra* note 35. The Virginia legislature passed a school vaccine requirement in 2007, and considered a bill that would delay that requirement, but the Senate Committee declined to take action on the bill. *Id.* D.C.’s bill was enacted and the requirement started at the

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trend supports the idea that mandatory HPV vaccination is an unnecessary measure at this point—especially when there is an increasing amount of vaccine skeptics.<sup>269</sup> Even without a mandatory requirement, an increasing number of females are currently obtaining the HPV vaccination.<sup>270</sup>

Recently, concerns regarding a connection between autism and vaccinations have fueled the battle over vaccines,<sup>271</sup> and as a result, parents are paying close attention to vaccine requirements and their right to decide what is best for their child.<sup>272</sup> Indeed, the use of exemptions is increasing.<sup>273</sup> Unfortunately, this increase in the use of exemptions has already led to an observable rise in vaccine-preventable disease,<sup>274</sup> with major outbreaks of measles and pertussis.<sup>275</sup> For example, states “with easily obtained exemptions had higher non-medical exemption rates and increased incidence of pertussis.”<sup>276</sup>

As states continue to consider the contentious subject of whether or not to require girls to be vaccinated against HPV, it is imperative that the state legislatures consider not only the effect of the mandate itself, but also the effect of any opt-out provisions the legislature chooses to include. Including the HPV vaccination on the list of mandated vaccines for school-entry with broad opt-out provisions will only encourage the use of exemptions, thereby undermining our nation’s public health. The development of vaccines was one of the “great public health achievements of the twentieth century,”<sup>277</sup> resulting in a dramatic decrease in common childhood illnesses that “once accounted for

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beginning of the 2009 school year. *Id.*

<sup>269</sup> Steinhauer & Harris, *supra* note 130.

<sup>270</sup> See Olmos, *supra* note 267.

<sup>271</sup> Park, *supra* note 139, at 36.

<sup>272</sup> See Steinhauer & Harris, *supra* note 130 (explaining that there is “an increasing number” of “vaccine skeptics” often due “to an unproven notion that vaccines are linked to autism and other disorders”).

<sup>273</sup> See *id.*

<sup>274</sup> *US Measles Increase Caused by Vacc Scare*, *supra* note 25.

<sup>275</sup> GOSTIN, *supra* note 6, at 380.

<sup>276</sup> *Id.*

<sup>277</sup> *Id.* at 376.

a substantial proportion of child morbidity.”<sup>278</sup> Although the approval of a vaccine against cancer-causing HPV strains is a tremendous step forward in improving our nation’s health, mandating its use will have an overall detrimental effect for it and other vaccines. Until states figure out an alternative to including broad opt-out provisions in their legislation, voluntary HPV vaccination is the best alternative.

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<sup>278</sup> *Id.*