

Seminar Paper – April 1, 2008

Legislative Responses to the HPV Vaccine: School Enrollment “Requirements” that are  
Optional to Parents

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During the prior two centuries state vaccination requirements have saved countless lives and reduced the incidence of several serious childhood diseases. Such requirements are an exercise of the government’s traditional role in promoting public welfare through the police power. Courts have upheld such requirements and recognized that states have broad discretion in promoting public health. Despite the benefits of widespread vaccination and legislative discretion in requiring such measures, vaccination requirements are not without controversy: they invade the body and restrict individual choice in personal matters.

Recently, the introduction of a vaccine that promises to save lives by reducing the incidence of cervical cancer has renewed the ever-lively debate over how state legislatures can or should ensure widespread vaccination. Proposed school enrollment requirements for the new vaccine are unique in that they include only female students. Some parents who are not otherwise opposed to school vaccination requirements have opposed a new requirement for this vaccine because it protects against a sexually transmitted infection. Unfortunately, legislatures have responded to opposition by considering new school vaccination requirements that would allow parents to excuse their children from the new vaccine requirement for any reason. Because the mandatory nature of school vaccine requirements has been pivotal to their success in eliminating

diseases, such broad opt out provisions that weaken the government's ability to fulfill its public health role should not be considered.

## **Introduction: An HPV Vaccine**

Merck recently marketed Gardasil, a vaccine which prevents infection with two types of human papillomavirus (HPV) which cause approximately 70% of cervical cancer and two other types of HPV which cause 90% of genital warts.<sup>1</sup> HPV is transmitted primarily through sexual contact, and can also be passed by an infected mother to a newborn.<sup>2</sup> Currently, HPV is the most common sexually transmitted infection in the U.S.<sup>3</sup>

In 2006 Gardasil was approved by the U.S. Federal Drug Administration (FDA) for distribution to females aged 9 to 26.<sup>4</sup> Subsequently, the Centers for Disease Control and Prevention (CDC) recommended the vaccine for females aged 11 and 12. The vaccine is considered most effective in pre-teen individuals because an optimal immune response is achieved at that age and because individuals that are not yet sexually active are less likely to already be infected with the HPV types that the vaccine guards against.<sup>5</sup> The American Association of Pediatrics has issued recommendations consistent with

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<sup>1</sup> Merck, Information About Gardasil, <http://www.gardasil.com> (last visited Mar. 27, 2008); Centers for Disease Control and Prevention (CDC), Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2007;56 (No. RR-2):2, 16, *available at* <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

<sup>2</sup> Mayo Clinic, HPV Infection: Causes, <http://www.mayoclinic.com/health/hpv-infection/DS00906/DSECTION=3> (last visited Mar. 5, 2008).

<sup>3</sup> CDC, Genital HPV Infection - CDC Fact Sheet, What is genital HPV infection?, <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm#Whatis> (last visited Mar. 5, 2008).

<sup>4</sup> U.S. Food and Drug Administration, News Release, FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health, June 8, 2006, *available at* <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.

<sup>5</sup> CDC, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2007;56(No. RR-2):16, *available at* <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

those of the CDC.<sup>6</sup> State legislatures and health agencies are currently considering measures to promote voluntary vaccination or to require the vaccine for school enrollment, and so far the issue has proven divisive.<sup>7</sup>

Part I briefly lays out the current scope and traditional justifications for state school vaccination requirements. Part II discusses the legal and policy implications of potential HPV vaccination requirements for school enrollment, highlighting in particular the controversies created by vaccinating teenagers against sexually transmitted infections and by requiring vaccinations for female, but not male, students. Part III reviews four types of initiatives actually considered by state legislatures in response to the availability of the HPV vaccine. Part IV concludes that school vaccination requirements for the HPV vaccine would be consistent with legal precedent and highly effective in preventing HPV infection and cervical cancer. Further, part IV argues that legislatures should not allow parents to easily exclude students from HPV vaccination requirements, because such special opt-out provisions would strip public health authorities of their traditional authority to implement community immunization initiatives and would undermine the government's purpose in preventing death and illness caused by cervical cancer.

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<sup>6</sup> American Academy of Pediatrics, Committee on Infectious Diseases, Policy Statement, Prevention of Human Papillomavirus Infection: Provisional Recommendations for Immunization of Females With Quadrivalent Human Papillomavirus Vaccine, May 23, 2007, *available at* <http://www.cispimmunize.org/ill/pdf/HPVprovisional.pdf>.

<sup>7</sup> After the Governor of Texas issued an order to make Texas the first state to require HPV vaccinations for girls entering the sixth grade, the legislature swiftly overrode the order. Office of the Governor, Rick Perry, Executive Order RP65 - February 2, 2007, Relating to the immunization of young women from the cancer-causing Human Papillomavirus, *available at* <http://www.governor.state.tx.us/divisions/press/exorders/rp65>; House Bill 1098, Session 80, May 8, 2007, *available at* <http://www.legis.state.tx.us/BillLookup/History.aspx?LegSess=80R&Bill=HB1098>.

On the other hand, in New Mexico, the Governor vetoed a bill passed by the legislature that would have required HPV vaccinations for sixth grade girls. 2007 Regular Session, SB1174 - HPV Vaccine in School-Based Clinics, *available at* [http://legis.state.nm.us/lcs/\\_session.asp?chamber=S&type=++&number=1174&Submit=Search&year=07](http://legis.state.nm.us/lcs/_session.asp?chamber=S&type=++&number=1174&Submit=Search&year=07).

## II. Overview of School Vaccination Requirements

Vaccination laws became common in the U.S. as early as the nineteenth century, when states began requiring students to receive a smallpox vaccination prior to attending school.<sup>8</sup> Vaccination has proven to be a highly effective and relatively inexpensive means for preventing the spread of infectious disease; widespread vaccination in the U.S. has significantly reduced illnesses and deaths attributable to diseases like measles and rubella and has even eliminated polio.<sup>9</sup>

The CDC now recommends that children receive eleven different vaccinations during the first six years of life.<sup>10</sup> All states currently require schoolchildren to be vaccinated for diphtheria, tetanus, pertussis (whooping cough), measles, rubella, and polio.<sup>11</sup> Most states require schoolchildren to be vaccinated for hepatitis B (47 states), mumps (47 states), and varicella (chickenpox, 42 states),<sup>12</sup> and require college entrants to be vaccinated for meningitis (34 states).<sup>13</sup> Six states also require schoolchildren to be vaccinated for hepatitis A.<sup>14</sup>

Courts have long approved of vaccination mandates as a valid exercise of the state's police power. In *Jacobson v. Massachusetts*, decided in 1905, the Supreme Court upheld a city regulation requiring that inhabitants be vaccinated for smallpox during a

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<sup>8</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 32 (1905) (discussing state laws conditioning public school attendance on vaccination for smallpox).

<sup>9</sup> CDC, Basics and Common Questions: What Would Happen If We Stopped Vaccinations?, <http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm#intro> (last visited Feb. 25, 2008).

<sup>10</sup> CDC, Recommended Immunization schedules for persons aged 0–18 years—United States, 2008. *MMWR* 2007;56(51&52):Q2, available at <http://www.cdc.gov/mmwr/pdf/wk/mm5701-Immunization.pdf>.

<sup>11</sup> Sabin Vaccine Institute, Immunization Requirements by State - 2007, [http://sabin.org/files/PDF/immunization\\_schedule\\_2007.pdf](http://sabin.org/files/PDF/immunization_schedule_2007.pdf) (last visited Mar. 5, 2008).

<sup>12</sup> *Id.*

<sup>13</sup> Immunization Action Coalition, Meningococcal Prevention Mandates for Colleges and Universities, <http://www.immunize.org/laws/menin.htm> (last visited Feb. 29, 2007).

<sup>14</sup> *Id.*

local outbreak of the disease.<sup>15</sup> The Court emphasized the broad discretion which states exercise in promoting public health and safety, and found the mandate to be reasonably aimed at serving a legitimate public health necessity, and therefore a permissible infringement of individual rights.<sup>16</sup> The Supreme Court later held that local officials may exclude from school those children failing to meet school vaccination requirements.<sup>17</sup> Courts have confirmed a state's authority to exclude unvaccinated children from public school even where the disease being vaccinated against was not present in the community.<sup>18</sup>

In addition to the preservation of public health and safety, other legitimate state interests support enactment of vaccination mandates. For example, school vaccination requirements can be justified under the state's traditional authority, under the doctrine of *parens patriae*, to protect minors.<sup>19</sup> Economic savings have also been cited as a justification for vaccination mandates, since vaccinations are an inexpensive means for preventing potentially costly diseases.<sup>20</sup>

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<sup>15</sup> Jacobson v. Massachusetts, 197 U.S. 11, 27–30 (1905).

<sup>16</sup> Jacobson v. Massachusetts, 197 U.S. 11, 27–30 (1905).

<sup>17</sup> Zucht v. King, 260 U.S. 174, 175 (1922).

<sup>18</sup> Maricopa County Health Dept. v. Harmon, 750 P.2d 1364 (Ariz. 1987) (approving exclusion of unvaccinated children from public schools even though disease being vaccinated against was not present in community).

<sup>19</sup> Frederic E. Shaw, *New Adolescent Vaccines: Legal and Legislative Issues*, 35 J.L. MED. & ETH. 106, 108 (2007) (citing doctrine of *parens patriae* as justification for vaccine requirements aimed at preventing diseases in children or incompetent persons).

<sup>20</sup> Frederic E. Shaw, *New Adolescent Vaccines: Legal and Legislative Issues*, 35 J.L. MED. & ETH. 106, 108 (2007) (citing societal economic savings as additional justification for vaccine requirements aimed at preventing non-infectious diseases, such as tetanus); see *Immunization: An Investment, Not an Expense - Preventive Medicine: Strategies For Quality Care and Lower Costs – Illustration*, BUSINESS & HEALTH, March 1995, available at [http://findarticles.com/p/articles/mi\\_m0903/is\\_n3\\_v13/ai\\_16899088](http://findarticles.com/p/articles/mi_m0903/is_n3_v13/ai_16899088) (citing 1994 study by Battelle Memorial institute which concluded that every dollar spent on childhood immunization saved as much as \$8.80 in direct medical costs); CDC, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2007;56(No. RR-2):15, "Cost Effectiveness of HPV Vaccine," available at <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

In *Jacobson*, the Court opined that the vaccination mandate must implicitly contain exceptions for those cases when an individual's physical condition created a specific risk of harm, making vaccination "cruel and inhuman."<sup>21</sup> Indeed, all fifty states provide statutory medical exemptions for school vaccination requirements.<sup>22</sup>

Most state statutes also provide a religious exemption to school vaccination requirements; such exemptions apply to those belonging to a religious group which dictates against vaccination, or for whom vaccination violates a personally held religious belief.<sup>23</sup> State courts have concluded, however, that the Free Exercise Clause does not require such religious exemptions.<sup>24</sup> Indeed, the Supreme Court has held that the Free Exercise Clause does not preclude the state from legislating in the interest of the public health. The Court upheld a child labor law used to convict a member of the Jehovah's Witnesses after her child helped distribute religious pamphlets. It reasoned that both the state's police power and its role as *parens patriae* justified the restriction of parental control in the interest of public health and the child's welfare. It even noted that a parent "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to

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<sup>21</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905).

<sup>22</sup> National Conference of State Legislatures (NCSL), State Statutory Laws Concerning School Vaccination Exemptions, <http://www.ncsl.org/programs/health/SchoolExempLawsChart.htm> (last visited Mar. 1, 2008).

<sup>23</sup> Mississippi and West Virginia do not provide a religious exemption. NCSL, State Statutory Laws Concerning School Vaccination Exemptions, <http://www.ncsl.org/programs/health/SchoolExempLawsChart.htm> (last visited Mar. 1, 2008).

<sup>24</sup> *See Wright v. DeWitt School Dist. No. 1 of Arkansas County*, 385 S.W.2d 644 (1965) (Free Exercise Clause does not require state to provide religious exemption for vaccination mandate); *see also Brown v. Stone*, 378 So.2d 218, 223 (Miss., 1979) ("To the extent that [the state vaccination requirement] may conflict with the religious beliefs of a parent, however sincerely entertained, the interests of the school children must prevail."); *see also Prince v. Massachusetts*, 321 U.S. 158 (1944).

expose the community or the child to communicable disease or the latter to ill health or death.<sup>25</sup>

The requirements for meeting a statutory religious exemption differ from state to state. Recent litigation has raised issues such as whether it is constitutional to limit such exemptions to those belonging to certain organized religions,<sup>26</sup> what beliefs qualify as religious beliefs,<sup>27</sup> and whether the state may inquire into the nature and sincerity of the beliefs claimed.<sup>28</sup>

Some states also allow an exemption for those who object to vaccination on philosophical grounds.<sup>29</sup> Unlike most religious exemptions, philosophical exemptions can sometimes be exercised selectively as to certain vaccinations but not others.<sup>30</sup>

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<sup>25</sup> Prince v. Massachusetts, 321 U.S. 158, 166-167 (1944).

<sup>26</sup> See *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (W.D. Ark. 2002) (restricting exemption to only those individuals belonging to certain organized religions violates Free Exercise Clause and Equal Protection Clause); *Sherr v. Northport-East Northport Union Free School District*, 148 F. Supp. 81, 91, 97 (E.D.N.Y. 1987) (limiting a religious exemption to those belonging to a “recognized religious organization” violated Establishment Clause); *but see Kleid v. Board of Educ.*, 406 F. Supp. 902 (W.D. Ky. 1976) (no violation of Establishment Clause). See generally, Comment: *The Religious and Philosophical Exemptions to State-Compelled Vaccination: Constitutional and Other Challenges*, 7 U. PA. J. CONST. L. 1101.

<sup>27</sup> See, e.g., *Farina v. Bd. of Educ. of the City of New York*, 116 F. Supp. 2d 503 (S.D.N.Y.) (beliefs actually held were personal and medical and not religious); *Matter of Christine M.*, 595 N.Y.S.2d 606 (Fam. Ct. 1992) (objection to the measles vaccine was based on medical and scientific concerns rather than religious beliefs); *Mason v. General Brown Cent. School Dist.*, 851 F.2d 47 (2d Cir. 1988) (applying New York law) (objection to immunizations as being contrary to the “genetic blueprint” intended by nature was based on parent’s chiropractic ethic rather than religious beliefs).

<sup>28</sup> See *In re Exemption from Immunization Requested by Susan Lepage v. State*, 2001 WY 26 (Wyo. 2001) (state statute did not allow health agency to inquire into the validity or nature of a mother’s asserted religious objections to Hepatitis B vaccine); *In re LePage*, 18 P.3d 1177 (Wyo. 2001) (state statute did not allow health agency to require more than written objection from mother). Other courts have been willing to inquire into a parent’s purported religious beliefs. See *supra* note 27.

<sup>29</sup> Currently eighteen states provide a philosophical exemption for school vaccination requirements. CDC, *Childcare and School Immunization Requirements 2005–2006*, <http://www.cdc.gov/vaccines/gen/laws/downloads/izlaws05-06.pdf> (last visited Mar. 5, 2008).

<sup>30</sup> See Note, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1344 (2004).

## II. Legal and Policy Implications of HPV Vaccination Requirements

The question of whether to expand current school vaccine requirements as new vaccines become available always involves numerous important policy concerns. The cost, safety, effectiveness, and available quantity of the vaccine, as well as alternative methods available to control a disease, all factor into the determination of whether the benefits of a vaccine requirement outweigh the public and private costs of such a program.<sup>31</sup>

For example, those opposed to HPV vaccination requirements have cited the high cost of Gardasil,<sup>32</sup> the limited duration of completed safety and efficacy studies, and the effectiveness of other available medical treatments at screening and treating cervical cancer.<sup>33</sup> Such issues have been highlighted by interest groups and weighed by state authorities in determining how to promote HPV immunization. This section will not exhaustively repeat all of the concerns raised by the HPV vaccine, but rather will focus on issues raised by two distinctive aspects of potential HPV vaccine requirements.

First, the sexually-transmitted nature of HPV infection has provoked debate over whether a school vaccine requirement is appropriate for such infections. Second, the fact that the vaccine primarily guards against cervical cancer, a gender-specific disease, will likely provoke debate over whether it is appropriate to include male students in any HPV vaccine requirement.

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<sup>31</sup> James J. Hodge Jr., NCSL State Legislative Report: Analysis of State Actions on Important Issues, School Vaccination Requirements: Legal and Social Perspectives, August 2002, <http://www.ncsl.org/programs/health/slr2714.htm> (describing historical and modern arguments surrounding state vaccination requirements).

<sup>32</sup> At \$360 for three required doses, the HPV vaccine is the most expensive vaccine recommended by the CDC. CDC, CDC Vaccine Price List, Feb. 5, 2008, at <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>.

<sup>33</sup> Sigrid Fry-Revere, *The Rush to Vaccinate*, N.Y. TIMES, Mar. 25, 2007.

## ***A. Vaccinating pre-teens against sexually transmitted infection***

Because the HPV vaccine protects against a sexually transmitted infection, proposed HPV vaccination requirements for eleven and twelve year old female students have proven controversial. Critics of school vaccination requirements for sexually transmitted diseases argue that school requirements are not justified for a vaccine that protects against so-called “behaviorally transmitted” diseases rather than diseases like smallpox, which spread through casual contact in the school environment.<sup>34</sup>

However, the fact that HPV is transmitted through sexual contact does not make a vaccination mandate for school enrollment less justifiable. A school HPV vaccination requirement targeting eleven and twelve year old female students would be reasonably related to a legitimate public health need.<sup>35</sup> The high rate of HPV infection in the U.S. and its connection to cervical cancer illustrate the public health necessity of an HPV vaccination. The greater effectiveness of the vaccine when administered to pre-teens illustrates the reasonableness of a school HPV vaccination requirement.

In fact, current school vaccination requirements reflect the fact that states have a legitimate interest in promoting public health through school vaccination requirements even for diseases that cannot be spread from student to student in the school setting. All states require students to be vaccinated for tetanus, even though tetanus is caused by

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<sup>34</sup> See, e.g., Linda Klepacki, Focus on the Family, Take Action: How to Guide HPV Vaccine Policy Decisions at the State Level, Jan. 18, 2007, *available at* [http://www.citizenlink.org/pdfs/fosi/abstinence/HPV\\_Vaccine\\_Alternative\\_Legislation.pdf](http://www.citizenlink.org/pdfs/fosi/abstinence/HPV_Vaccine_Alternative_Legislation.pdf); Andrea Lafferty, Executive Director, The Traditional Values Coalition, No Mandatory HPV Vaccine For Girls!, Feb. 21, 2007, *available at* <http://www.traditionalvalues.org/modules.php?sid=3015> (“HPV is not a communicable disease; it is a disease resulting from intimate sexual contact. All vaccines should be voluntary unless there is a clear and present danger to the public health from a communicable disease such as Polio or Tuberculosis.”)

<sup>35</sup> See *Jacobson v. Massachusetts*, 197 U.S. 11, 27–30 (1905).

wound infection and is not contagious.<sup>36</sup> Nearly all states also require schoolchildren to be vaccinated against Hepatitis B, which is primarily transmitted through sexual contact or use of an infected needle.<sup>37</sup> Introduction of the Hepatitis B vaccine in 1999 did raise concerns from some that vaccination requirements were not appropriate for ‘behaviorally transmitted’ diseases.<sup>38</sup> However, initial attempts to distribute the vaccine to ‘at risk’ populations were almost entirely ineffective, and legislatures eventually adopted school or newborn vaccination requirements that have successfully reduced the incidence of Hepatitis B in children and adults.<sup>39</sup>

The prevalence of HPV infection in the U.S. suggests that HPV vaccination is a legitimate public health necessity. In a 2007 study, 26.8% of women aged 14 to 59 tested positive for HPV infection, with the highest rate of infection seen in women aged 20 to 24.<sup>40</sup> Over 15% of the women in the study tested positive for “high-risk,” or cancer-causing, types of HPV.<sup>41</sup> Those engaging in “safe” sex are still at risk of becoming infected, since condoms may not prevent transmission of HPV, which occurs through skin-to-skin contact.<sup>42</sup> Even those who choose to delay all sexual contact until marriage

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<sup>36</sup> CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases 74-75* (Atkinson W, Hamborsky J & McIntyre L, Wolfe S, eds. 10th ed. Washington DC: Public Health Foundation 2007), available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/tetanus.pdf>

<sup>37</sup> *Id.*

<sup>38</sup> See Note, *Taking Account of Partial Exemptors in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1351-54 (2004) (describing opposition to Hepatitis B vaccination requirements based on Hepatitis B’s means of transmission)

<sup>39</sup> Jane E. Brody, *Personal Health*, NY TIMES, Sept. 11, 1991, at C12. (explaining necessity for CDC’s recommendation of hepatitis B vaccine for newborns); CDC, *What would happen if we stopped vaccinating?*, <http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm#hepb> (“The number of new infections per year has declined from an average of 450,000 in the 1980s to about 80,000 in 1999. The greatest decline has occurred among children and adolescents due to routine hepatitis B vaccination”).

<sup>40</sup> Eileen F. Dunne, MD, MPH, et. al, *Prevalence of HPV Infection Among Females in the United States*, 297 J. AM. MEDICAL ASSOC’N 813 (2007).

<sup>41</sup> Eileen F. Dunne, MD, MPH, et. al, *Prevalence of HPV Infection Among Females in the United States*, 297 J. AM. MEDICAL ASSOC’N 813 (2007).

<sup>42</sup> Mayo Clinic, *HPV Infection: Prevention*, at <http://www.mayoclinic.com/health/hpv-infection/DS00906/DSECTION=8> (last visited Mar. 5, 2008); CDC, *Genital HPV Infection - CDC Fact*

may not be able to protect themselves from eventual exposure to HPV infection through unwanted sexual contact, or through marital sex with a previously infected spouse.

Surveys of teenage sexual activity reveal that it is reasonable to require STD-preventing vaccines for pre-teens. One national survey concluded that 24% of females in the U.S. became sexually active by the age of fifteen, and that the percentage increased to 40% by age sixteen and 70% by age eighteen.<sup>43</sup> Even those teenagers who choose not to engage in sexual intercourse may be at risk for HPV infection, since HPV can also be transmitted through ‘foreplay’.<sup>44</sup>

A school HPV vaccination requirement would survive a constitutional challenge asserting an infringement of the right of parents to control their children’s sexual education. Groups which advocate an “abstinence-only” approach to preventing the transmission of sexually transmitted infections argue that HPV vaccination requirements will promote pre-marital sex or promiscuity among teenagers.<sup>45</sup> Parents do have a protected right to control the education of their children.<sup>46</sup> For example, in *Alfonso v. Fernandez* a federal court held that a school condom distribution program violated parents’ due process rights under the Fourteenth Amendment by operating without

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Sheet, How can people prevent HPV?, <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm#prevent> (last visited Mar. 5, 2008).

<sup>43</sup> CDC, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), March 12, 2007 / 56(Early Release);1-24, available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm?s\\_cid=rr56e312a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm?s_cid=rr56e312a1_e).

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

<sup>45</sup> Andrea Lafferty, Executive Director, The Traditional Values Coalition, *No Mandatory HPV Vaccine For Girls!*, Feb. 21, 2007, available at <http://www.traditionalvalues.org/modules.php?sid=3015> (“Mandating a vaccine for a sexually-transmitted disease sets a bad precedent that could be used to mandate condoms for boys and girls and birth control pills for girls on school campuses. Such mandates would be a financial boon to the manufacturers of drugs and condoms for sex, but will undermine parental rights and encourage girls and boys to believe they are immune from the effects of premarital sexual activities.”).

<sup>46</sup> *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923)

parental consent.<sup>47</sup> The court reasoned that although the state had a compelling interest in preventing the spread of AIDS, the distribution program was not necessary to serve that interest, since the program could be operated with a parental opt out right and because students could easily obtain condoms outside of the program.<sup>48</sup> By contrast, another federal court found a similar program constitutional because student participation was entirely voluntary.<sup>49</sup>

Despite the outcome in *Alfonso*, a school HPV vaccination requirement should not be viewed as infringing a parent's right to influence their child's sexual education. Even if distribution of a prophylactic interferes with parental rights by sending teenagers the message that sexual intercourse is safe or permissible, the distribution of an HPV vaccine would not. The HPV vaccine is a longterm preventive measure that is intended to be administered well before individuals become sexually active, while a condom is only useful once one has become sexually active.<sup>50</sup> Therefore, administering the vaccine does not assume teenage sexual activity in the same way that condom distribution might.

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<sup>47</sup> *Alfonso v Fernandez*, 606 N.Y.S.2d 259, 265-67 (N.Y. App. Div. 1993) (“The petitioners enjoy a well-recognized liberty interest in rearing and educating their children in accord with their own views”); *but see* *Cornwell v State Board of Education*, 314 F. Supp. 340 (Md. D.C. 1969), *aff’d* 428 F.2d 471 (4th Cir.) (“The plaintiffs further assert that they have the exclusive constitutional right to teach their children about sexual matters in their own homes, and that such exclusive right would prohibit the teaching of sex in the schools. No authority is cited in support of this novel proposition, and this Court knows of no such constitutional right.”).

<sup>48</sup> *Alfonso v Fernandez*, 606 N.Y.S.2d 259, 265-67 (N.Y. App. Div. 1993) (“Because the Constitution gives parents the right to regulate their children's sexual behavior as best they can, not only must a compelling State interest be found supporting the need for the policy at issue, but that policy must be essential to serving that interest as well.”). *See generally* Bjorklun, *Condom Distribution in the Public Schools: Is Parental Consent Required?*, 91 EDUC. L.R. 11 (1994).

<sup>49</sup> *See* *Curtis v School Comm.*, 652 NE2d 580 (1995) (condom distribution plan did not infringe on parents' interests in directing sex education because plan was not compulsory for students); *see also* *Parents United for Better Schs., Inc. v. School Dist. of Phila.*, 148 F.3d 260 (3d Cir. 1998) (voluntary condom distribution plan that allows parents to exclude their children does not violate the Fourteenth Amendment).

<sup>50</sup> The vaccine is known to be effective for at least three years; studies with a longer duration are underway. CDC, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MMWR 2007;56 (No. RR-2):2, 16, *available at* <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

Further, the HPV vaccine guards against just one type of sexually transmitted infection, and does not prevent pregnancy. Therefore, administering the vaccine does not purport to make sex ‘safe’ in the same way that condom distribution might.

Further, the right of a parent to control the health decisions of minors is arguably diminished with regard to preventing sexually transmitted infections.<sup>51</sup> The privacy interests of a minor to make decisions with respect to their body and the interests of the state in protecting the minor are both heightened in matters related to prevention of sexually transmitted disease. Indeed, state laws commonly allow minors to consent, without parental approval, to health procedures that prevent, diagnose, or treat sexually transmitted disease.<sup>52</sup>

In addition, given the effectiveness of school vaccination requirements in particular in reducing the spread of disease, a court would likely find that an HPV vaccination requirement is sufficiently tailored to the state’s compelling interest in preventing the spread of disease.

Even if a school HPV vaccination requirement is a constitutional exercise of the states’ police power, some parents will remain opposed to the requirement and will seek to be exempted from the requirement based on their fear that it promotes immoral or risky behavior. In states where a philosophical exemption to school vaccination requirements is available,<sup>53</sup> parents will already have a mechanism to avoid an HPV

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<sup>51</sup> Abigail English, *New Adolescent Vaccines: Legal and Legislative Issues*, 35 J.L. MED. & ETH. 106, 109-10 (2007) (“The most common category of minor consent laws based on the services a minor seeking is one that includes prevention, diagnoses, or treatment of sexually transmitted disease (STD). . . . There are variations in terminology and technical details, but every state allows minors to consent, at least in some way, for the diagnosis and treatment of STDs or venereal diseases.”).

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

<sup>53</sup> Currently eighteen states provide a philosophical exemption for school vaccination requirements. CDC, *Childcare and School Immunization Requirements 2005 –2006*, <http://www.cdc.gov/vaccines/gen-laws/downloads/izlaws05-06.pdf> (last visited Mar. 5, 2008).

vaccination requirement based on their moral viewpoint, should they choose to do so. However, parents residing in Mississippi and West Virginia, where only a medical exemption to school vaccination requirements is available, will find no mechanism to exempt their children from an HPV vaccination requirement based on moral opposition.

Constitutional challenges against HPV vaccination requirements based on the Free Exercise Clause of the First Amendment will not likely succeed in those states. The Mississippi Supreme Court has held that the state's interest in immunizing schoolchildren against "crippling and deadly" diseases is compelling and it overrides the religious interests of an objecting parent.<sup>54</sup> This is the prevailing view. The Supreme Court has held that a "valid and neutral law of general applicability" that incidentally interferes with an individual's religious beliefs does not violate the Free Exercise Clause,<sup>55</sup> and has noted in dicta that "The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."<sup>56</sup>

Even in those states where a religious exemption is available by statute, such an exemption might not allow parents to exclude their children from an HPV vaccination requirement based on a personal sense of morality. Some states require that parents belong to an organized religion which dictates against all vaccines in order to claim the exemption.<sup>57</sup> Other states require only that vaccination be in conflict with the parent's sincerely held religious beliefs. However, these states may scrutinize the parents'

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<sup>54</sup> Brown v. Stone, 378 So.2d 218, 220-23 (Miss. 1979); *see also* Wright v. DeWitt School Dist. No. 1 of Arkansas County, 385 S.W.2d 644 (1965) (Free Exercise Clause does not require state to provide religious exemption for vaccination mandate).

<sup>55</sup> Employment Division v. Smith, 494 U.S. 872 (1990) (state's prohibition of peyote use did not violate Free Exercise Clause).

<sup>56</sup> Prince v. Massachusetts, 321 U.S. 158, 166-167 (1944).

<sup>57</sup> Such requirements have been held by some state courts to violate the First Amendment. *See supra* note 26.

purported belief and reject a claimed exemption based on a belief that is not religious in nature.<sup>58</sup>

Further, parents in some states can not exercise religious exemptions selectively as to certain vaccines.<sup>59</sup> However, as a practical matter, this would not be a problem in the case of the HPV vaccine: a parent attempting to get a religious exemption for their eleven or twelve year old will already have benefited by immunizing their child against most of the diseases included in the CDC's childhood immunization schedule and would likely be allowed to claim the religious exemption despite the prior immunization history.<sup>60</sup>

### ***B. Vaccinating females only, or vaccinating males against cervical cancer***

A second distinct characteristic of currently-proposed HPV vaccination requirements is the exclusion of male students. Proposed school requirements mirror the current FDA approval and CDC recommendations, which include only females. While the vaccine has been tested for safety in males, its efficacy for prevention of disease in males is still under investigation.<sup>61</sup> Approval for distribution to males is possible within the next year.<sup>62</sup>

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<sup>58</sup> For example, a belief that the vaccine would encourage promiscuous sexual activity and expose a teenager to other health threats would not be a 'religious' objection to the vaccine. *See supra* note 27.

<sup>59</sup> *See Note, Taking Account of Partial Exemptions in Vaccination Law, Policy, and Practice*, 36 CONN. L. REV. 1341, 1344 (2004).

<sup>60</sup> *See id.*; CDC, Recommended Immunization schedules for persons aged 0–18 years—United States, 2008. MMWR 2007;56(51&52):Q2, available at <http://www.cdc.gov/mmwr/pdf/wk/mm5701-Immunization.pdf>.

<sup>61</sup> Mayo Clinic, HPV Infection: Prevention, at <http://www.mayoclinic.com/health/hpv-infection/DS00906/DSECTION=8> (last visited Mar. 5, 2008); CDC, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2007;56(No. RR-2):17, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

<sup>62</sup> Jan Hoffman, *Vaccinating Boys For Girls' Sake?*, N.Y. TIMES, Feb. 24, 2008, Style Desk 1.

Vaccination requirements for female students could be seen as problematic because a vaccination requirement including only one-half of the disease-transmitting population will not be effective in stopping the spread of HPV.<sup>63</sup>

An HPV mandate for female students could also be seen as a violation of the Equal Protection Clause. Challenges of a female-only vaccination requirement on that ground could be reviewed under an intermediate level of scrutiny, requiring that the gender classification be substantially related to an important government interest.<sup>64</sup>

Requiring HPV vaccinations for female students—those students at risk of developing cervical cancer—would be substantially related to the important government interest of preventing cancer. Women are not similarly situated with men in that only women are at risk of developing cervical cancer. At-risk groups can be singled out for mandatory measures aimed at preventing the spread of disease. For example, populations at risk for transmitting or becoming infected with HIV (including prostitutes, drug users, and prison inmates) can be subjected to mandatory testing. Such testing has been reviewed and upheld under rational basis scrutiny.<sup>65</sup>

However, women *are* situated similarly with men in that both genders can be infected by and transmit HPV. The inclusion of only one-half of the disease transmitting population would not be substantially related to the purpose of *preventing HPV transmission*, since such a requirement would be vastly under-inclusive.

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<sup>63</sup> For many diseases, vaccination of over 80% of the population is required to effectively stop the spread of the disease. See CDC & World Health Org., History and Epidemiology of Global Smallpox Eradication, Slide 16-17, *available at* <http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradicationhistory.pdf>.

<sup>64</sup> See Tuan Anh Nguyen v. I.N.S., 533 U.S. 53 (2001) (requiring that the classification be substantially related to an important governmental objective); U.S. v. Virginia, 518 U.S. 515 (1996) (requiring an exceedingly persuasive justification for the classification); J.E.B. v. Alabama ex rel. T.B., 511 U.S. 127 (1994) (applying heightened scrutiny).

<sup>65</sup> See A. Alyce Werdel, *Mandatory AIDS Testing: the Legal, Ethical and Practical Issues*, 5 NOTRE DAME J.L. ETHICS & PUB. POL'Y 155, 205-13 (1990).

Future vaccination requirements could potentially include females and males; but these requirements could also be seen as problematic. Parents may be unwilling to vaccinate their sons, who are not at risk of developing cervical cancer, and who will receive the risks but not the primary benefits of the vaccine.<sup>66</sup> The HPV vaccine does have certain benefits for males: it prevents infection with the types of HPV causing 90% of genital warts, and may protect against more rare forms of cancer (including penile and anal cancer).<sup>67</sup> In addition, men who are vaccinated against HPV infection will receive a significant benefit in that they will be protected against an infection that could be transmitted to future sexual partners, and could lead to their serious illness or death. Further, general vaccine mandates are permissible even when some who bear the burden of being vaccinated are not included in the group primarily benefited. Currently, states require that all schoolchildren receive the rubella vaccination, even though the primary purpose for the vaccination is to prevent congenital rubella syndrome which can occur in infants born to infected mothers.<sup>68</sup> As with the HPV vaccine, the rubella vaccine also protects men from less common complications, including Encephalitis and arthritis.<sup>69</sup>

A future HPV vaccination including both male and female students is preferable to one including only female students. The primary justification for mandatory vaccination programs is the benefit of ceasing transmission of the disease within the population that is achieved only with high rates of immunization. An HPV vaccination

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<sup>66</sup> Jan Hoffman, *Vaccinating Boys For Girls' Sake?*, N.Y. TIMES, Feb. 24, 2008, Style Desk 1.

<sup>67</sup> CDC, Genital HPV Infection - CDC Fact Sheet, How common are HPV and related diseases?, at <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm#common> (last visited Mar. 5, 2008).

<sup>68</sup> CDC, Epidemiology and Prevention of Vaccine-Preventable Diseases 160 (Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 10th ed. Washington DC: Public Health Foundation, 2007), available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf>.

<sup>69</sup> CDC, Epidemiology and Prevention of Vaccine-Preventable Diseases 160 (Atkinson W, Hamborsky J & McIntyre L, Wolfe S, eds. 10th ed. Washington DC: Public Health Foundation 2007), available at <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf>.

requirement should be designed to achieve community-wide benefits by including the entire disease-transmitting population in any requirement.

### **III. Legislative Responses to the Availability of Gardasil**

At least forty-one states have introduced legislation to promote HPV vaccination since Gardasil was first approved in 2006. These states have considered legislation in four major areas: (1) requiring HPV vaccination for girls entering sixth grade, (2) requiring schools or health departments to inform students or parents of the availability and purpose of HPV vaccination, (3) educating the general public regarding HPV vaccination, and (4) funding HPV vaccination for girls in select age ranges or requiring private insurers to cover HPV vaccination.<sup>70</sup>

#### ***A. Vaccination Requirements for School Enrollment***

By early 2008, at least two jurisdictions have instituted a school HPV vaccination requirement. In the District of Columbia, parents of girls entering the sixth grade must certify that they have received the HPV vaccine, that they are claiming a medical or religious exemption, or that they have decided to opt out of the requirement.<sup>71</sup> In order to opt out, parents do not have to provide a reason for doing so, but they must sign a document stating that they have been informed about the HPV vaccination requirement.<sup>72</sup>

Virginia has instituted a requirement with a similar opportunity for parents to opt out after receiving information about the vaccine.<sup>73</sup> The statute expresses the reasoning behind the broad opt out rights: “Because the human papillomavirus is not communicable

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<sup>70</sup> NCSL, HPV Vaccine, Feb. 2008, <http://www.ncsl.org/programs/health/HPVvaccine.htm>.

<sup>71</sup> D.C. Code § 7-1651.04 (b).

<sup>72</sup> D.C. Code § 7-1651.04 (b).

<sup>73</sup> Va. Code Ann. § 32.1-46(D)(3).

in a school setting, a parent or guardian, at the parent or guardian's sole discretion, may elect for their child not to receive the human papillomavirus vaccine."<sup>74</sup>

On the other hand, an HPV vaccination requirement has been expressly rejected in at least three states. A 2007 Arizona statute took the determination of whether to require the HPV vaccine out of the discretion of the state's health agency.<sup>75</sup> New Mexico's legislature passed a requirement similar to those in D.C. and Virginia, which was vetoed by the governor, who asserted that such a requirement was premature.<sup>76</sup> In Texas, it was the governor who attempted to implement an HPV vaccine requirement through an executive order.<sup>77</sup> Allegations about Merck's role in influencing the order raised severe criticism. The Texas legislature overrode that order with subsequent legislation.<sup>78</sup>

Several states have considered, but not adopted, vaccination requirements with parental opt out rights.<sup>79</sup> Other states have considered HPV vaccination requirements that lack special opt out provisions, so that parents would have only the medical, religious, or

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<sup>74</sup> Va. Code Ann. § 32.1-46(D)(3).

<sup>75</sup> A.R.S. § 36-672(c)

<sup>76</sup> 2007 Regular Session, SB1174 - HPV Vaccine in School-Based Clinics, available at [http://legis.state.nm.us/lcs/\\_session.asp?chamber=S&type=++&number=1174&Submit=Search&year=07](http://legis.state.nm.us/lcs/_session.asp?chamber=S&type=++&number=1174&Submit=Search&year=07). The governor stated "there is insufficient time to educate parents, schools and health care providers." <http://www.foxnews.com/story/0,2933,263824,00.html>.

<sup>77</sup> Office of the Governor, Rick Perry, Executive Order RP65 - February 2, 2007, Relating to the immunization of young women from the cancer-causing Human Papillomavirus, *available at* <http://www.governor.state.tx.us/divisions/press/exorders/rp65>.

<sup>78</sup> Tex. Educ. Code § 38.001(b-1).

<sup>79</sup> Two mandates with parental opt out provisions have been proposed during the 2007-2008 legislative session. H.R. 396 (Kentucky 2008); S. 244 (N.M. 2008). Several others were proposed in the prior session. *E.g.*, S. 80 (Colorado 2007); H.R. 4104, H.R. 4164, S. 132, S. 133 (Michigan 2007); S.F. 243 (Minnesota 2007), S. 4394, A. 5810 (N.Y. 2007); H.R. 81 (Ohio 2007); H.R. 345 (Kentucky 2007); S. 660 (Florida 2007).

philosophical exemptions normally available to them under the state's school vaccination scheme.<sup>80</sup>

## ***B. Measures to Support Voluntary Vaccination***

States have considered promoting voluntary vaccination by requiring schools or a state health agency to distribute information about HPV, its connection to cervical cancer, and the availability of the HPV vaccine to certain students, to their parents, or both. At least six states have adopted a parental notification scheme.<sup>81</sup> Four states now require that such information be provided to certain students, either through existing sex education curriculum or through separate written materials.<sup>82</sup>

Other legislation directs state agencies or special task forces to plan and implement awareness campaigns to educate the general public about HPV, its connection to cervical cancer, and the availability of the HPV vaccine. At least five states have instituted such a campaign.<sup>83</sup>

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<sup>80</sup> See A. 16 (California 2007) (withdrawn); H.R. 6977 (Connecticut 2007); S. 155 (Georgia 2007); H.R. 2227 (Kansas 2007); H.R. 143 (Kentucky 2007); S. 54 (Maryland 2007) (withdrawn); S. 102 (Mass. 2007); H.R. 895 (Miss. 2007); S. 847 (Oklahoma 2007); H.R. 3136 (South Carolina 2007) (tabled); H.R. 2835 (West Virginia 2007).

<sup>81</sup> See § 410 I.L.C.S. 315/2e (Illinois) (Department of Public Health must provide written information to female students entering sixth grade and their parents); Burns Ind. Code Ann. § 20-34-4-3(b) (2007) (Indiana) (school must provide information to parents of students entering sixth grade); N.J. Stat. § 18A:40-42 (2007) (New Jersey) (school district must provide HPV educational fact sheet to parents of students in seventh grade); N.C. Gen. Stat. § 115C-47 (North Carolina) (school must provide information to parents of students entering grades five through twelve); Tex. Educ. Code § 38.001(b-1) (Texas) (Health and Human Services Commission must provide information about HPV that is "unbiased, medically and scientifically accurate, and peer reviewed" to parents of students "at the appropriate time in the immunization schedule"); Rev. Code Wash. (ARCW) § 28A.210.080 (Washington) (schools must provide information to parents of students entering sixth grade or higher).

<sup>82</sup> See C.R.S. 22-1-110.5 (Colorado) (sex education programs must emphasize abstinence as a means of preventing HPV infection, but must also provide information about available HPV vaccine); § 410 ILCS 315/2e (Illinois) (the Department of Health must provide information to female students entering sixth grade); H.F. 611 (Iowa) (school must provide information to students in seventh grade); 22 MRSA §3174-LL Sec. A-1 (Maine) (information must be distributed via posters in high schools, pamphlets distributed to fifth grade students, and educational activities in schools).

<sup>83</sup> See H.R. 1471, Chapter No. 232 (North Dakota 2007); Utah Code Ann. § 26-7-3 (2007); Cal. Health & Saf. Code § 104200; S. 45, 22 MRSA §3174-LL Sec. A-1 (Maine 2007); Tex. Educ. Code § 38.001(b-1); N.J. Stat. § 26:4-95.4.

Several states have enacted measures to provide the HPV vaccination free of cost to certain females. One approach is to require private insurers to include the vaccine in their coverage and to publicly fund vaccinations for underinsured women within a target age group.<sup>84</sup> Another approach is to provide the vaccine free of cost through the department of health for all women within the target age group.<sup>85</sup> Federal funding for the HPV vaccine is also available to underinsured, Medicaid-eligible children through the Vaccines for Children Program.<sup>86</sup>

## IV. Recommendations

State legislation adding the HPV vaccine to the list of vaccines already required for school enrollment would be consistent with legal precedent. States have an interest in promoting the public welfare by immunizing schoolchildren against HPV infection in order to reduce the incidence of cervical cancer. The government's role in protecting the interests of minors and in reducing the societal costs of disease would also justify an HPV vaccination requirement for sixth grade students.

Vaccination mandates are a highly effective means for reducing or eliminating the presence of communicable diseases, like HPV, in a population. School enrollment requirements are especially effective in ensuring a sufficient level of participation to

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<sup>84</sup> 20 I.L.C.S. 2310/2310-617 (Illinois) (females under 18); C.R.S. 22-1-110.5; Sec. A-1 (Colorado) (underinsured female minors).

<sup>85</sup> 22 M.R.S.A. §3174-LL (Maine) (devoting public funds to HPV vaccination of girls aged eleven and twelve); H.R. 1061 (South Dakota) (reserving \$9.2 million to fund HPV vaccination of girls aged eleven to eighteen).

<sup>86</sup> Merck, New Data Presented on GARDASIL®, Merck's Cervical Cancer Vaccine, in Women Through Age 45, "GARDASIL is widely available throughout the United States," Nov. 5, 2007, *available at* [http://www.merck.com/newsroom/press\\_releases/product/2007\\_1105.html](http://www.merck.com/newsroom/press_releases/product/2007_1105.html); CDC, Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2007;56(No. RR-2):19, *available at* <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

achieve “herd immunity”<sup>87</sup> and in ensuring participation by segments of the population less likely to learn about or have the funds for beneficial vaccinations.<sup>88</sup>

Other legislative attempts to promote HPV vaccination will not be as effective as a school enrollment requirement in preventing the spread of HPV infection.<sup>89</sup> Information distribution schemes will likely influence some parents to have their children vaccinated. However, parents that are likely to take the initiative to act on such information are already likely to take their children to regular physician visits and immunize them based on a doctor’s recommendations.<sup>90</sup> Public funding of HPV vaccines similarly relies on parents to take the initiative to get their children vaccinated, and does not ensure increased vaccination levels.

Any HPV vaccination requirement should not include a special parental opt out provision. Many legislatures have reacted to public backlash against potential requirements by considering or adopting requirements that allow parents to easily opt out of an HPV vaccination requirement. Unlike religious exemptions, these special opt out provisions don’t require parents to provide a reason for their choice. The only requirement is that parents receive certain information about HPV infection and the

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<sup>87</sup> The goal of reducing overall vulnerability to a disease in the population is termed “herd immunity”—and it is achieved when enough members of a population are vaccinated that the likelihood that a disease will be transmitted to an unvaccinated person is effectively removed. Jan Hoffman, *Vaccinating Boys For Girls’ Sake?*, N.Y. TIMES, Feb. 24, 2008, Style Desk 1.

<sup>88</sup> James G. Hodge Jr., NCSL, NCSL State Legislative Report, Analysis of State Actions on Important Issues, School Vaccination Requirements: Legal and Social Perspectives, Aug. 2002, Volume 27, Number 14, available at <http://www.ncsl.org/programs/health/slr2714.htm>.

<sup>89</sup> *But see* Comment, *The Human Papillomavirus Vaccine: Should it be Mandatory or Voluntary?*, 10 J. HEALTH CARE L. & POL’Y 421 (2007) (arguing that mandatory HPV vaccination in children wrongfully intrudes on parental interests and asserting that voluntary vaccination combined with public funding are sufficient to achieve benefits of HPV vaccine); Note, *Mandatory Cervical Vaccinations*, 35 J.L. MED. & ETHICS 495, 496 (2007) (commenting that HPV vaccination mandates without parental opt out rights will cause public backlash).

<sup>90</sup> See CDC, Genital HPV Infection - CDC Fact Sheet, How can people prevent HPV-related diseases?, <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm#preventrelated> (last visited Mar. 1, 2008); CDC, Genital HPV Infection - CDC Fact Sheet, Is there a treatment for HPV?, <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm#treatment> (last visited Mar. 1, 2008).

vaccine and return documentation to the school stating that they wish their child to be excluded.

Such an approach would contravene attempts to reduce cervical cancer, and undermine the government's role in promoting public health. As discussed below, this special opt out approach is undesirable because it will (1) create the perception that vaccination requirements are optional, (2) lead to over-exemption, and (3) exclude from the requirement many teenagers who are, or soon will be, at risk of HPV infection.

First, an HPV vaccination 'requirement' that allows parents to opt out for any reason will set a precedent that vaccination decisions should be made by individuals and not by public health authorities. This would reverse the traditional approach to preventing communicable diseases, under which the state's implementation of public health measures can not be subverted by individual dissenters.<sup>91</sup>

Traditionally, public health authorities gauge the risks and public benefits of a vaccine to determine whether a mandate will promote public health. If individuals are allowed to determine whether the individual benefits of a vaccine outweigh the attendant risks, a "free rider" problem develops. Because widespread vaccination reduces the incidence of communicable diseases and the individual risk of infection, at some point, the risks to an individual of being vaccinated will outweigh the individual risk of infection, and a rational individual will refuse to be vaccinated. However, if all individuals are allowed to engage in this risk-benefit analysis and opt out of the

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<sup>91</sup> "We are unwilling to hold it to be an element in the liberty secured by the Constitution of the United States that one person, or a minority of persons, residing in any community and enjoying the benefits of its local government, should have the power thus to dominate the majority when supported in their action by the authority of the State." *Jacobson v. Massachusetts*, 197 U.S. 11, 37-38 (1905).

vaccination, incidence of the disease will again increase, and the benefits for the overall population will vanish.

Even prior to the introduction of an HPV vaccine, many have noted a disturbing trend toward broader exemptions from vaccination requirements. More people have been exercising philosophical exemptions,<sup>92</sup> leading a few states to get rid of that exemption. Where enough members of a population are allowed to exclude themselves from a vaccination requirement, the population becomes vulnerable to disease outbreaks. Recently, states with higher rates of exemption have experienced higher incidence of pertussis, and outbreaks of measles have been noted in religious groups with high rates of exempting members.<sup>93</sup> The trend toward emphasizing personal choice in vaccination determinations can potentially reverse all of the disease reduction achieved through vaccination.

Second, the opt-out approach will lead to over-exemption. Unlike current religious exemptions, special opt-out approaches are not sufficiently limited. Religious exemptions properly balance individual interests against the government's role in promoting public health. Religious exemptions excuse from vaccination requirements only the small number of individuals whose religious beliefs dictate against immunization. They apply only to those individuals for whom the issue of vaccination is significant, and don't allow individuals to excuse themselves from vaccination

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<sup>92</sup> "The authors found that between 1991 and 2004 the percentage of children whose parents had chosen to exempt them from vaccines increased by 6 percent per year, resulting in a 2.5-fold increase." Dr. Paul Offit, *Vaccines and Preventable Diseases: Fatal Exemption: Relationship Between Vaccine Exemptions and Rates of Disease*, Jan. 29, 2007, *available at* <http://www.cdc.gov/vaccines/gen/laws/fatal-exemption.htm>.

<sup>93</sup> *Id.*; *see also* CDC, *Measles in a Population with Religious Exemption to Vaccination – Colorado*, Nov. 29, 1985 / 34(47);718-20, <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000644.htm>; CDC, *Outbreak of Measles --- San Diego, California, January--February 2008*, Feb. 22, 2008 / 57 (Early Release);1-4, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e222a1.htm> (last visited Mar. 1, 2008).

requirements as a matter of convenience. Because they are limited in this way, they don't undermine the success of a community-wide vaccination program.

By contrast, a special vaccine-specific opt out provision that demands no justification from parents does not strike the proper balance between individual interests and public health goals. Such opt out provisions make exemption easier and cheaper than compliance, and will result in many parents excusing their children from the vaccine requirement as a matter of convenience. Such unlimited exemption defeats the purpose of community-wide vaccination programs, which is to ensure a sufficient level of immunization to effectively cease transmission in the population.

Finally, the opt-out approach will result in many teenagers being excluded from the HPV vaccination requirement despite the fact that they would benefit from it. Parents have a prerogative to influence the sexual education of their children, but they may be poor evaluators of the necessity of the HPV vaccine. Because many teenagers may not be frank about their sexual activity, many parents will not be able to objectively evaluate whether their child is at risk for HPV infection.

## **Conclusion**

Mandatory HPV vaccination is consistent with longstanding precedent that personal liberty and discretion can be limited in the interest of public health. State legislatures should not implement voluntary vaccination "requirements" that shift public health decisionmaking from the state to parents.

Rather than including overly-broad opt out provisions in an HPV vaccination requirement, states should delay legislation and adopt mandates only after general

awareness and acceptance of the HPV vaccine has been achieved through educational campaigns.<sup>94</sup>

A delayed vaccination requirement will provide other benefits as well. Later HPV vaccination mandates will be more effective in that they will likely include male students.<sup>95</sup> In fact, the D.C. statute already provides that the district's vaccination program should be extended to men consistent with CDC recommendations.<sup>96</sup> Delayed action will also allow legislatures to review longterm studies of the efficacy and safety of the vaccine. Mandating a vaccine before the longterm effects are fully known could lead to unnecessary adverse effects and could severely damage public acceptance of public health initiatives. Delayed action is especially appropriate in the case of HPV vaccination decisions, since Merck's extensive lobbying efforts in 2006 have provoked a great deal of unease and suspicion. Merck stands to earn substantial profits from early HPV vaccination requirements, since its vaccination will remain the only one in the U.S. market until at least 2009.<sup>97</sup>

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<sup>94</sup> See Rebecca E. Skov, *Examining Mandatory HPV Vaccination for all School-Aged Children*, 62 FOOD & DRUG L.J. 805 (2007) (recommending mandatory HPV vaccination); Note, *The HPV Vaccine: Necessary or Evil?*, 19 HASTINGS WOMEN'S L.J. 149, 167 (2008) (noting that public education campaigns may be necessary prior to rollout of HPV vaccination mandates).

<sup>95</sup> For many diseases, vaccination of over 80% of the population is required to effectively stop the spread of the disease. See The CDC and the World Health Organization, *History and Epidemiology of Global Smallpox Eradication*, Slide 16-17, available at <http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradicationhistory.pdf>.

<sup>96</sup> D.C. Code § 7-1651.04 (b).

<sup>97</sup> A delay in the FDA approval process for rival GlaxoSmithKline means that its vaccine, Cervarix, will not be marketed prior to 2009. *Glaxo sends warning on 2008 earnings*, INT'L HERALD TRIBUNE, Feb. 7, 2008. The two vaccines are both approved in European markets and available at comparable prices. *Id.*; Andrew Jack, *Sanofi dismisses GSK cancer vaccine*, FIN. TIMES, Feb. 6 2008, available at [http://us.ft.com/ftgateway/superpage.ft?news\\_id=fto020620081932377080&page=1](http://us.ft.com/ftgateway/superpage.ft?news_id=fto020620081932377080&page=1). Unlike Gardasil, Cervarix does not guard against genital warts. Aaron Smith, *Glaxo fires shot over Merck's bow: Glaxo launches study comparing experimental cervical cancer vaccine to Merck's Gardasil*, CNNMoney.com, Jan. 18 2007, <http://money.cnn.com/2007/01/18/news/companies/glaxo/index.htm>.