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**ETHICAL, LEGAL, AND ECONOMIC  
CONSIDERATIONS RELATED TO THE MANDATORY  
ADMINISTRATION OF THE HUMAN  
PAPILLOMAVIRUS VACCINE**

COLLEEN S. WALTER\*

I. INTRODUCTION

Human papillomavirus (HPV), the most common sexually transmitted infection, is a group of more than forty related viruses.<sup>1</sup> HPV is transmitted through genital contact and can infect cells on the surface of the skin, genitals, anus, mouth, and throat.<sup>2</sup> HPV types sixteen and eighteen cause 70% of cervical cancer, 30% of vaginal and vulvar cancer, and 80% of anal cancer, while HPV types six and eleven cause over 90% of the cases of anogenital warts in both men and women.<sup>3</sup> HPV is most common among women ages twenty to twenty-four, with a prevalence rate of 45% in this age group, and remains at a rate of 20% for women ages fifty to fifty-nine.<sup>4</sup> Studies suggest that 80% of sexually active females will contract the virus before the age of fifty.<sup>5</sup>

It is estimated that approximately twenty million Americans are currently infected with HPV and that an additional six million people become infected each year.<sup>6</sup> Most who become infected with HPV are unaware because the body is typically able

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1. *Genital HPV Infection—CDC Fact Sheet*, CTNS. FOR DISEASE CONTROL & PREVENTION (Aug. 25, 2011) [hereinafter *CDC Fact Sheet*], available at <http://www.cdc.gov/std/hpv/HPV-Factsheet-Aug-2012.pdf>.

2. *Cervical Cancer*, AM. CANCER SOC'Y (Jan. 18, 2012), <http://www.cancer.org/Cancer/CervicalCancer/DetailedGuide/index>. HPV can even circumvent the protection of condoms. *Id.*

3. Harrell W. Chesson et al., *Cost-Effectiveness of Human Papillomavirus Vaccination in the United States*, 14 EMERGING INFECTIOUS DISEASES 244, 244 (2008).

4. *Cervical Cancer*, *supra* note 2.

5. Christina O. Hud, Note, *The Virginia Gardasil Law: A Constitutional Analysis of Mandated Protection for Schoolchildren Against the Human Papillomavirus*, 17 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 223, 226–27 (2010).

6. *CDC Fact Sheet*, *supra* note 1.

to clear the infection on its own.<sup>7</sup> However, in those cases caused by high-risk oncogenic HPV types, the infection can become chronic and frequently causes cervical cancer.<sup>8</sup> Cervical cancer is one of the most common female malignancies worldwide.<sup>9</sup> In 2012, an estimated 12,170 new cases of invasive cervical cancer will be diagnosed in the United States alone and 4220 women will die from the disease.<sup>10</sup>

In June 2006, the Food and Drug Administration (FDA) approved a new vaccine for women, Gardasil, produced by the pharmaceutical company Merck, that protects against infection by certain strains of HPV, including the two strains that cause most cases of cervical cancer.<sup>11</sup> This quadrivalent vaccine is intended to prevent four strains of HPV associated with cervical cancer, precancerous genital lesions, and genital warts, and has been approved by the FDA for use in girls and women ages nine to twenty-six. Since the vaccine has the greatest benefit when it is administered before a person becomes sexually active, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention recommends that the target population for routine immunization should be adolescents who are

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7. *Cervical Cancer*, *supra* note 2. Because most HPV strains do not cause pain or have easily recognizable symptoms, many people do not know they are infected or that they are transmitting the virus to a partner. Additionally, an individual can develop HPV even after years have passed since the last sexual contact with an infected person because certain strains linger in the body. This lack of recognition or awareness of transmission makes HPV prevention especially difficult. *Id.*

8. *Id.*

9. Pang-Hsiang Liu et al., *Cost-Effectiveness of Human Papillomavirus Vaccination for Prevention of Cervical Cancer in Taiwan*, 10 BMC HEALTH SERVS. RES. 11, 11 (2010). Only breast cancer, accounting for twelve percent of all female cancers, is ahead of cervical cancer in terms of deadliest female diseases. *Id.*

10. *Cervical Cancer*, *supra* note 2.

11. *HPV Vaccine: Implementation and Financing Policy in the U.S.*, HENRY J. KAISER FAMILY FOUND., [http://www.kff.org/womenshealth/upload/7602\\_02.pdf](http://www.kff.org/womenshealth/upload/7602_02.pdf) (last visited Apr. 4, 2013) [hereinafter *HPV Vaccine*]. Controversially, the FDA also approved Gardasil for men in October of 2009. Many opponents of the mandatory vaccine for females have angrily pointed to the Equal Protection Clause of the Constitution as a defense. As an example, Dr. Anne Szarewski, a clinical consultant at Cancer Research UK, has said, “vaccinating only girls is a shortsighted and potentially damaging strategy . . . [and] reinforces the idea that sexual health is solely a female concern . . . .” Rebecca E. Skov, *Examining Mandatory HPV Vaccination for All School-Aged Children*, 62 FOOD & DRUG L.J. 805, 817 (2007); see also Lawrence O. Gostin, *Mandatory HPV Vaccination and Political Debate*, 306 J. AM. MED. ASS’N 1699, 1700 (2011) (discussing how the “lack of gender equity remains ethically troubling” and that the HPV vaccine is the first mandated for only one gender). Although equal protection issues will not be addressed in this Note, the continuing controversy over a mandatory HPV vaccine for males will be a fascinating debate to watch unfold in the near future.

approximately twelve years of age, while women ages thirteen to twenty-six should be given a “catch-up” vaccination.<sup>12</sup> Research suggests “[t]he efficacy of this vaccine is almost 100% if given to young women before sexual exposure.”<sup>13</sup> However, “[w]omen already infected with HPV [may still] benefit from the vaccine because it can prevent infection by other HPV strains not yet contracted.”<sup>14</sup> In order to be effective, Gardasil must be injected in three doses over six months.<sup>15</sup> Before the development of HPV vaccines like Gardasil, a widely used screening procedure known as a Papanicolaou (Pap) test provided the most effective avenue for preventing cervical cancer.<sup>16</sup> The Pap test, which detects changes in the cervix before cancer develops, remains critical for early detection even in those who have received the HPV vaccine.<sup>17</sup>

Recognizing the significance of the vaccine, legislatures across the country quickly proposed new laws requiring vaccination for school-age girls. The ethical and legal issues surrounding mandatory HPV vaccination for school-age girls has generated significant public debate. As such, Part II of this Note will summarize the major arguments that have been presented on both sides of the debate, discuss state legislative activity concerning the vaccine, and explore the boundaries of vaccination exemptions. While the strong push-back from various interest groups is understandable, this Note will support moving towards mandatory vaccination while recognizing the necessity for exemptions, ongoing education, and a sensitivity to opposing views. Part III will explore the strengths and weaknesses of an economic analysis of mandatory HPV vaccination. This Note will argue that as societies with finite resources cope with the fundamental question of what an extra year of life is worth, sophisticated economic analyses regarding the cost-effectiveness of the HPV vaccine and other types of medical care will become increasingly influential.

From the outset, it is important to understand that the epidemic of cervical cancer and other HPV-related diseases is different than epidemics that have led to mandatory vaccination in the past. The issues surrounding HPV vaccination are more complex and controversial. Unlike the airborne diseases which have warranted mandatory vaccinations, HPV is influenced by personal

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12. *HPV Vaccine*, *supra* note 11.

13. Chesson et al., *supra* note 3, at 244.

14. *HPV Vaccine*, *supra* note 11.

15. *Id.*

16. *Cervical Cancer*, *supra* note 2.

17. *HPV Vaccine*, *supra* note 11.

risk-taking sexual behavior. In fact, the HPV vaccine is the first example where the nature of the activity required to contract the disease is the primary source of controversy.<sup>18</sup> As such, debates concerning the vaccine are highly personal and highly charged, with strong moral and religious overtones.

Given that the FDA granted approval of Gardasil in 2006, the debate about the vaccine has only just begun. This Note is an opportunity to explore some of the ethical, legal, economic, and public policy issues of this debate as medical societies develop their recommendations, vaccination programs take shape within states, and legislatures and courts decide the correct balance between individual rights and the common good.

## II. THE DEBATE OVER MANDATING HPV VACCINATION

### A. *Public Resistance to Compulsory HPV Vaccination*

The relatively recent development of the HPV vaccine marks a major advance in public health. The vaccine has the potential to save millions of people from cancer and protect a broad population against painful HPV-related infections. Given these clear benefits, opposing government-mandated HPV vaccination may seem inexplicable or even irresponsible. However, this “miracle drug” has been resisted on philosophical, political, and ideological grounds.<sup>19</sup> Arguments against a mandated vaccine illuminate the unique ethical and legal issues surrounding laws making vaccination compulsory. A brief summary of the major issues raised is necessary before advocating for a cautious, yet receptive approach to a mandatory HPV vaccine.

First, opponents argue that mandating the HPV vaccine represents an encroachment on parental autonomy. The Supreme Court has long recognized that parental rights are fundamental and sanctified in the language of the Due Process Clause of the Fourteenth Amendment. The Court acknowledged this right in *Meyer v. Nebraska*, holding that parents have the right to “establish a home and bring up children.”<sup>20</sup> As such, requiring school-age girls to receive the vaccine “takes away the responsibility for par-

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18. Felicia B. Eshragh, Note, *Same Debate, Different Result: Parental Opt-Outs of a Mandated HPV Vaccine*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 205, 217 (2008).

19. Hud, *supra* note 5, at 224.

20. *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923). In *Prince v. Massachusetts*, the Supreme Court qualified the holding in *Meyer* and found that “the state has a wide range of power for limiting parental freedom and authority in things affecting the child’s welfare; and that this includes, to some extent, matters of conscience and religious conviction.” *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944). Basically, children should not be denied protection from HPV because of their parents’ personal beliefs. Hud, *supra* note 5, at 254.

ents to be the primary decision-makers regarding children's health . . . ."<sup>21</sup> From this perspective, whether or not to have a child receive a vaccine that protects against a sexually transmitted virus "should reside strictly within the family," and "[l]egislating its use is inappropriately paternalistic."<sup>22</sup> Parents concerned about the unknown long-term health effects of the vaccine argue that they should be able to "protect their children from the potentially ill effects of reckless public policy, and [that] their inability to do so is an affront to principles of individual justice."<sup>23</sup>

Arguments concerning the scope of parental autonomy are bolstered by the nature of the disease itself. HPV is not casually transmitted. Unlike diseases such as measles, smallpox, or chickenpox, HPV is not an airborne, highly infectious disease that is directly communicable in a school setting. As such, it is argued that "the government should not intervene when a virus can be curbed by changing behavior . . . ."<sup>24</sup> Given the marked differences in communicability when compared to other epidemic diseases, there is a "less compelling rationale for requiring protection against it . . . ."<sup>25</sup> Furthermore, some opponents argue that "[a]lthough it is true that many women suffer from cervical cancer, it is hardly a public health risk when compared to the millions affected by epidemics in the last century."<sup>26</sup> Therefore, it is argued, since the disease can be prevented through a change in behavior and since it does not amount to a public health emergency, requiring the vaccine represents an intrusive and unnecessary infringement on parental autonomy.

Additionally, concerns regarding excessive state police power have also been raised. Police power refers to the power of states under the Tenth Amendment to regulate matters affecting

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21. Chris Gaetano, *Bill Sparks Debate over Health vs. Parents' Rights*, SENTINEL (Feb. 21, 2007), [http://em.gmnews.com/news/2007-02-21/Front\\_page/014.html](http://em.gmnews.com/news/2007-02-21/Front_page/014.html) (internal quotation marks omitted).

22. T.P. Collins, *The HPV Vaccine*, CATH. MED. WKLY., Jan. 12, 2007, <http://cathmedweek.blogspot.co.uk/2007/01/hpv-vaccine.html>.

23. John D. Blum & Norchaya Talib, *Balancing Individual Rights Versus Collective Good in Public Health Enforcement*, 25 MED. & L. 273, 279 (2006).

24. Katherine S. Homan, Note, *Do the Ends Justify the Means? Compelling the Use of HPV Vaccination on Men*, 27 J. CONTEMP. HEALTH L. & POL'Y 183, 212 (2011).

25. James Colgrove, *The Ethics and Politics of Compulsory HPV Vaccination*, 355 NEW ENG. J. MED. 2389, 2390 (2006).

26. Homan, *supra* note 24, at 201–02. The note further argues that there are already ways for women to protect themselves, including Pap smears and more cautious sexual behavior. *Id.* at 202.

the health, safety, and general welfare of the public.<sup>27</sup> State police powers extend to inspection, quarantine, and health laws.<sup>28</sup> Arguments have been presented that “there is no legal support for state-mandated HPV vaccination laws because these mandates extend beyond a state’s power to compel vaccination as granted by the Supreme Court . . . and are in contravention of the U.S. Constitution.”<sup>29</sup>

Next, opponents argue that mandatory vaccination sends a message to young girls that pre-marital sex with multiple partners is both acceptable and expected. For many religious groups, and Catholics in particular, a mandated vaccine “undermine[s] abstinence-based prevention messages,”<sup>30</sup> and “sends a message to both children and society that sexual intercourse is acceptable behavior for pre-adolescents and adolescents as long as children are protected from the physical consequences of such conduct.”<sup>31</sup> As such, vocal Catholics contend that mandatory HPV vaccination violates the foundational teachings of the Catholic Church, and “neglects to consider the psychological consequences of adolescent sex.”<sup>32</sup> In a strongly-worded response to proposed legislation mandating the vaccine, an article in *Catholic Medical Weekly* concluded that “[r]equiring HPV immunizations for young girls . . . is . . . no different from requiring that all school age girls be put on contraception.”<sup>33</sup> Similarly, Focus on

27. Carrie A. Roll, Note, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*, 10 J. HEALTH CARE L. & POL’Y 421, 428–29 (2007).

28. *Gibbons v. Ogden*, 22 U.S. 1, 16 (1824).

29. Lindsey Heinz, Note, “*Please Don’t Shot My Daughter!*” *Is There Legal Support for State-Compelled HPV Vaccination Laws? Why Ethical, Moral, and Religious Opposition to These Laws May Be Jumping the Gun*, 56 U. KAN. L. REV. 913, 914 (2008).

30. Colgrove, *supra* note 25, at 2389; *see also* Christy Hoppe, *Perry Orders HPV Vaccine*, DALLAS MORNING NEWS, Feb. 3, 2007, [http://31.216.132.122/web/www.data-yard.net/10t2/cancer\\_vaccine\\_mandatory.htm](http://31.216.132.122/web/www.data-yard.net/10t2/cancer_vaccine_mandatory.htm) (presenting a similar idea that mandating the vaccine sends a message that the state expects young girls to have sex). *But see* God, Sex, Drugs and Politics: A New Vaccine Sparks Controversy, ECONOMIST, Feb. 8, 2007, <http://www.economist.com/node/8677214>. In response to arguments that his controversial executive order mandating the vaccine for school-age girls in Texas encourages promiscuity, Governor Rick Perry responded, “[i]f the medical community developed a vaccine for lung cancer . . . would the same critics oppose it, claiming it would encourage smoking?” *Id.*

31. Darryn Cathryn Beckstrom, Note, *Human Papillomavirus Vaccine Legislation: Are We Oversexualizing Our Youth?*, 2 U. ST. THOMAS J. L. & PUB. POL’Y 109, 114 (2008).

32. *Id.* at 110.

33. Collins, *supra* note 22. Although The National Catholic Bioethics Center authorized a statement that “[t]he NCBC considers HPV vaccine to be a morally acceptable method of protecting against this disease,” it asked that

the Family, a Christian group, has warned that “HPV vaccines do not, in any circumstance, negate or substitute the best health message of sexual abstinence until marriage and sexual faithfulness after marriage.”<sup>34</sup> In sum, the possibility of young girls viewing a mandated vaccine as an endorsement of promiscuous behavior has ignited forceful opposition from many religious groups.

Finally, opponents argue that it is important to remember Merck (a large pharmaceutical company) stands to make a substantial profit if mandatory HPV vaccination is enforced. If the vaccine is required as a condition for school entry across the country, Merck will make an enormous profit totaling billions of dollars. Not surprisingly, shortly after FDA approved the vaccine, Merck initiated an aggressive, nationwide lobbying campaign to convince state lawmakers to pass favorable legislation, and also attempted to influence professional medical societies to recommend the vaccine.<sup>35</sup> Thus, there is concern that Merck’s powerful financial incentive for widespread implementation complicates the development of a vaccination program designated as promoting the common good. Ultimately, opponents argue that Merck lacks transparency when it comes to harmful drugs, is driven by profit rather than the public good, and is generally undeserving of national trust and support.

In response, proponents counter that a mandated HPV vaccine does not unduly infringe upon parental autonomy and falls squarely within the state’s police power.<sup>36</sup> In *Jacobson v. Massachusetts*, the Supreme Court first addressed the issue of

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“civil authorities leave this decision to parents and not make such immunization mandatory.” *Id.*

34. Skov, *supra* note 11, at 822.

35. Roll, *supra* note 27, at 439; *see also* Katherine A. Fortune, Note, *Medical Miracle or Unnecessary Exercise? The Legal Implications of Mandatory Childhood Vaccination for HPV*, 85 U. DET. MERCY L. REV. 203, 214 (2008) (discussing how Merck is credited with “bankrolling efforts to pass state legislation across the country to vaccinate girls with Gardasil”). As an example of excessive lobbying, “Merck contributed close to \$40,000 to political campaigns in Virginia in 2005 and 2006.” Roll, *supra* note 27, at 439; *see also* Gostin, *supra* note 11, at 1700 (discussing how Merck “donated \$28,500 to [Rick Perry’s] gubernatorial campaign and an additional \$377,500 to the Republican Governors Association, for which Perry served as chairman”).

36. Indeed, the majority of courts support substantial deference to states’ police power to require vaccinations. Thus, “[c]ompulsory vaccination laws . . . enjoy broad judicial and constitutional support, but have also become the subject of growing resistance.” Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 388 (2004). It is interesting to note that the vaccine’s most prominent supporters are public health organizations including the Centers for Dis-

mandatory vaccinations, the scope of state police power, and the parameters of an individual's right to privacy.<sup>37</sup> Jacobson, a Massachusetts citizen, opposed the smallpox vaccine for philosophical reasons because he did not believe it was effective. After evaluating the Cambridge Board of Health's order to all city residents to receive the smallpox vaccine due to a smallpox outbreak in the city, the Court held that protection of the whole community trumps individual rights in such situations.<sup>38</sup> The Court determined that "the liberty secured by the Constitution of the United States . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint."<sup>39</sup> In fact, "[u]pon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members."<sup>40</sup> The Court thus firmly established the state's general authority to require immunization in the interest of public safety. In a subsequent case, *Zucht v. King*, the Supreme Court expanded the police power to encompass requiring mandatory vaccination as a condition of school attendance.<sup>41</sup> Applying *Jacobson*, the Court reasoned that "a state may, consistently with the federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative."<sup>42</sup>

Proponents of the vaccine therefore argue that, in certain circumstances, a parent's right to raise his or her child undisturbed is not absolute. They argue that "[m]inors have a right to be protected against vaccine-preventable illness, and society has an interest in safeguarding the welfare of children who may be harmed by the choices of their parents or guardians."<sup>43</sup> Additionally, HPV, the most common sexually transmitted infection, certainly qualifies as a public health threat. HPV is potentially deadly and has the ability to spread through society at a high

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ease Control and Prevention, the American Academy of Pediatrics, and the American Academy of Family Physicians. Gostin, *supra* note 11, at 1699.

37. 197 U.S. 11 (1905).

38. *Id.* at 27 (stating that the "community has the right to protect itself against an epidemic of disease which threatens the safety of its members"). As discussed, whether or not HPV is a true threat to the general welfare remains unsettled.

39. *Id.* at 26.

40. *Id.* at 27.

41. 260 U.S. 174 (1922).

42. *Id.* at 176.

43. Colgrove, *supra* note 25, at 2390.

rate. Thus, its “prevalence in society underscores a need to act.”<sup>44</sup>

Proponents have also countered that arguments regarding the sexual messages of the vaccine miss the point: “[i]t’s not about having sex or not having sex. It prevents cancer.”<sup>45</sup> As Kim Gandy, President of The National Organization for Women, states: “[o]pposing an effective vaccine that would save hundreds of thousands of women’s lives with the vacuous assertion that it would lead to promiscuity is inexcusable.”<sup>46</sup> Moreover, practicing pre-marital abstinence does not necessarily ensure that a woman will be protected from HPV. Women may contract the virus from their husbands or, unfortunately, fall victim to date rape or other types of sexual assault.<sup>47</sup> Finally, proponents urge that it is critical to recognize the “high prevalence of sexual conduct occurring among teens today.”<sup>48</sup> According to a national survey, 40% of females reported engaging in sexual activity by age sixteen, and 70% reported being sexually active by age eighteen.<sup>49</sup> Thus, a mandatory HPV vaccine would “promote sexual health and awareness,” and provide girls and women with the means to effectively prevent the disease.<sup>50</sup>

Ultimately, the debate over a mandated HPV vaccine has been focused on balancing the collective good against individual rights.<sup>51</sup> In fact, it has been suggested that “[f]ew areas in recent American public health regulation represent the clash of individual liberty and the protection of community health better than the current controversies over the efficacy and safety [of] mandatory childhood immunizations.”<sup>52</sup> In order to strike the necessary balance, policymakers must weigh interests on both sides of the scale: protecting privacy rights while looking out for the interests of the state. Protection of society demands that

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44. Jonathan T. Scott, Note, *The Difficult Road to Compelling Vaccination for Sexually Transmitted Diseases—How Gardasil and Those to Follow Will Change the Way That States Require Inoculation*, 97 Ky. L.J. 697, 719 (2009).

45. Janet Elliott & Todd Ackerman, *Perry Vaccine Move Stirs Money, Sexual Concerns*, Hous. Chron., Feb. 3, 2007, <http://www.chron.com/news/health/article/Perry-vaccine-move-stirs-money-sexual-concerns-1801490.php>.

46. Hud, *supra* note 5, at 242; *see also* Gostin, *supra* note 11, at 1700 (arguing that there is “no evidence that HPV vaccines increase sexual activity among adolescents”).

47. *See* Skov, *supra* note 11, at 822.

48. Hud, *supra* note 5, at 242.

49. *See* Eshragh, *supra* note 18, at 211.

50. Fortune, *supra* note 35, at 216.

51. *See* Homan, *supra* note 24, at 206 (“The American legal system aims to balance the rights of its citizens against the goals of society without upsetting either.”).

52. Blum & Talib, *supra* note 23, at 277.

“[w]here the threats to a population are most serious, individual rights must be subordinate to the common good.”<sup>53</sup>

Although strong arguments exist on both sides of the mandatory vaccination issue, concerns for the common good seem to outweigh protection of individual rights in this particular circumstance. As a New Jersey politician caught in the heat of the debate offered, “[t]here are few times where the Legislature can act to directly save lives. This is one of those times. We have the power to bring an end to a type of cancer . . . Lives are at stake, and we can save them.”<sup>54</sup> Research has proven that “school-based laws are an effective and efficient way of boosting vaccine-coverage rates.”<sup>55</sup> As previously discussed, the “vaccine has the potential to prevent many cases of cervical cancer and also reduce the cost and emotional burden for the millions of women who receive abnormal Pap test results attributable to HPV infection.”<sup>56</sup> The means to prevent a terrible disease have become available and administering the vaccine to the broadest population of people should be of paramount concern. While educational programs and other methods of persuasion may be marginally effective, requiring HPV vaccination by law will almost certainly achieve more widespread protection against the disease than will policies that rely exclusively on persuasion and education.

That being said, mandating the HPV vaccine as a condition for school entry at this time appears premature. As will be discussed in Part III, *infra*, too many unanswered questions remain about the vaccine, particularly with regards to long-term safety and efficacy. The recent hesitation of many states, explored in Part II.B, *infra*, suggests that although mandating the vaccine falls within the state’s police power and is the most effective means of promoting the public good, legislatures should hold off until more is known about the drug. As the debate evolves in the public arena and in the legislatures, it will be important to encourage continued research and analysis regarding the vaccine, strategies for its implementation, and the public health consequences, both expected and unexpected, of this new intervention.

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53. *Id.* at 274.

54. Gaetano, *supra* note 21.

55. Colgrove, *supra* note 25, at 2390–91; *see also HPV Vaccine, supra* note 11 (“Mandatory requirements associated with school entrance have been among the most effective methods for assuring that vaccines reach the largest share of the population.”).

56. *HPV Vaccine, supra* note 11.

Although HPV is markedly different from other diseases that have warranted compulsory vaccination in the past, it is nevertheless a major public health issue deserving of similar treatment. However, a more cautious approach is necessary at this point. This will allow time for more information to be gathered about the medical and public health aspects of HPV vaccination. Of equal importance, this will also permit a continued and vigorous discussion about the moral and religious issues involved so that deeply held convictions on all sides can be given the careful consideration they deserve. Given the unique moral and religious issues that are so entangled in this debate, a future mandatory HPV vaccination program must be sure to include well-delineated exemptions allowing people to opt-out for agreed-upon medical, religious, and philosophical reasons. Exemptions, especially on religious grounds, should be strongly supported.

As more states begin to implement HPV vaccination programs, economic analyses, discussed in Part III, *infra*, should play an increasingly influential role in guiding the implementation of mandatory vaccination programs, so that they not only promote the common good, but do so in the most sensible and cost-efficient manner.

#### B. *State Legislative Response to the HPV Vaccine*

Vaccination requirements for school admission are a matter of state law.<sup>57</sup> “The modern era of compulsory vaccination began in the 1970s to control indigenous measles, a communicable disease.”<sup>58</sup> The HPV vaccine has sparked a mixed response in legislatures across the country.

Since 2006, forty-one states and the District of Columbia have introduced legislation to educate the public about the HPV vaccine, and at least twenty-one states have enacted such legislation.<sup>59</sup> Some states, such as New Hampshire and South Dakota, provide the vaccine at no cost to girls between the ages of eleven and eighteen. Legislative action at the state level continues. As of March 2013, eight states had proposed HPV-related legislation for the 2013–2014 sessions.<sup>60</sup> Mandating the vaccine, however, remains controversial. While a few states have aggressively supported mandating the vaccine, “the morality question has super-

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57. See Eshragh, *supra* note 18, at 210 (“There are no vaccines mandated on the Federal level, only through state health departments.”).

58. Homan, *supra* note 24, at 188.

59. See *id.* at 211.

60. See *HPV Vaccine*, NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last updated Apr. 2013).

seded the public health goals in most state legislatures.”<sup>61</sup> Shortly after the Centers for Disease Control and Prevention approved the HPV vaccine for women, Rick Perry, the Governor of Texas, passed an executive order mandating the vaccine for all sixth-grade girls.<sup>62</sup> In defending the order, Perry stated that “[r]equiring young girls to get vaccinated before they come into contact with HPV is responsible health and fiscal policy that has the potential to significantly reduce cases of cervical cancer and mitigate future medical costs.”<sup>63</sup> Perry’s executive order, however, was “angrily overturned by the Texas legislature” just a few months later.<sup>64</sup> Similarly, the Michigan Senate introduced legislation requiring the vaccine for sixth-grade girls, but the bill was never enacted. Today, only Virginia and the District of Columbia have approved school attendance mandates for sixth-grade girls.<sup>65</sup> In Virginia, the possible exemptions for the vaccine are broad, and parents may easily “opt-out” of the vaccine for their own personal reasons.<sup>66</sup>

### C. *The Boundaries of Vaccination Exemptions*

“All states recognize some form of exemption from mandatory vaccinations.”<sup>67</sup> Exemptions may be based on medical, religious, or philosophical grounds. For medical exemptions, a doctor must sign a statement declaring that a particular vaccine would be harmful to the health of the patient.<sup>68</sup> A religious exemption is available for those who believe that administration of vaccines is contrary to their religious beliefs.<sup>69</sup> In general, courts construe religious exemptions strictly, and insist that opposition to compulsory vaccination be “genuine, sincere, and an integral part of the religious doctrine.”<sup>70</sup> The least common type is the philosophical exemption, which allows parents and children an exception for a philosophical objection to vaccines that is not based on spiritual or religious grounds.<sup>71</sup> For philo-

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61. Eshragh, *supra* note 18, at 210.

62. Tex. Exec. Order No. RP65 (Feb. 2, 2007).

63. Elliott & Ackerman, *supra* note 45.

64. E.G., *The HPV Vaccine: Jabs All Around*, *ECONOMIST*, Sept. 13, 2011, <http://www.economist.com/blogs/democracyinamerica/2011/09/hpv-vaccine>.

65. *HPV Vaccine*, *supra* note 60, at 212.

66. Eshragh, *supra* note 18, at 212–13.

67. *Id.* at 216.

68. *Id.*

69. *Id.*

70. Roll, *supra* note 27, at 431.

71. Eshragh, *supra* note 18, at 216.

sophical exemption, many states require that individuals object to all vaccines, not just a particular vaccine.<sup>72</sup>

Exemptions for mandatory immunizations conflict with the public health concept of “herd immunity.”<sup>73</sup> Herd immunity is “achieved when an ‘entire community is protected against a contagion because a sufficiently large percentage of the group is immune.’”<sup>74</sup> As vaccination levels increase, the entire population gains resistance to the disease.

Although the benefits of herd immunity are significant and the reasoning behind the concept is persuasive, future state legislation concerning mandatory HPV vaccination should include well-delineated religious exemptions. No other mandatory vaccination program has been so closely linked with individual moral and religious beliefs. An appreciation of this delicate interplay is necessary for a fair administration of the vaccine. While the benefits of herd immunity may be compromised by ensuring the availability of exemptions, those parents who, in good faith, believe that the vaccine violates fundamental religious teachings should not be forced to comply with the requirement. Religious exemptions for a mandated HPV vaccine, therefore, are both necessary and just.

### III. AN ECONOMIC ANALYSIS OF THE HPV VACCINE

#### A. *Evaluating the Efficacy of HPV Vaccination*

Spearheaded by Judge Richard Posner,<sup>75</sup> a Law and Economics approach to public policy and legal decisions encourages judges to “engage in cost-benefit, economic analysis of law on the ground that wealth-maximization [is] a kind of preeminent, legitimizing principle of political and legal authority.”<sup>76</sup> Encompassed within the Law and Economics discipline is the belief that individuals, societies, and legal systems should pursue effi-

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72. *Id.*

73. For a strong argument against liberal exemptions, see Skov, *supra* note 11, at 818. Skov argues that “[h]erd immunity is threatened as more and more parents free ride off the community’s dwindling immunity . . . .” (quoting Steve P. Calandrillo, *supra* note 36, at 353).

74. Homan, *supra* note 24, at 191.

75. It is widely accepted that Richard Posner has played the most critical role in broadening the scope of Law and Economics throughout the academic community. His work, *The Economic Analysis of Law*, provided “the single most forceful impetus to the onslaught of economics into law schools.” John J. Donohue III, *Law and Economics: The Road Not Taken*, 22 LAW & SOC’Y REV. 903, 911 (1988). The influence of the movement “has been in no small part due to the clarity and accessibility of all of Posner’s work.” *Id.* at 912.

76. Jed Rubenfeld, *A Reply to Posner*, 54 STAN. L. REV. 753, 766 (2002).

ciency—“getting the most desirable results from the least resources.”<sup>77</sup> From an economics perspective, greater efficiency is always a top priority. Economic analyses of healthcare initiatives have become increasingly visible in the public policy and public health arenas, and have also been the subject of controversy. Debates concerning how to use a finite amount of money in a healthcare system which has a seemingly infinite number of demands have raised uncomfortable issues, including how to prioritize available resources.<sup>78</sup> Although far from perfect, mathematical models that attempt to determine the economic impact of various healthcare programs can be informative and contribute to policy discussions in a substantive way. The HPV vaccine provides an especially rich opportunity for economic analysis, given the availability of fairly well-developed mathematical models concerning the disease and the many public health professionals involved in this area.

A useful economic model of HPV vaccination must account for the many variables involved and set clear, easily definable outcomes. However, given the complexity of the disease and the relatively recent introduction of the vaccine into the marketplace, this remains a daunting task demanding a combination of sophisticated methodology and reliance upon unsupported assumptions. By taking a brief look at the many uncertainties that currently affect the validity of cost-effectiveness analyses regarding HPV vaccination, an appreciation of the difficulties inherent in this approach will be clear.

First, the HPV vaccine, although powerful, is no panacea; in fact, it could end up being associated with significant untoward consequences. According to the Centers for Disease Control and Prevention, the HPV vaccine is an important layer of protection, but it is “not a shortcut to prevention.”<sup>79</sup> As such, regular Pap tests retain a critical role in the primary prevention of cervical cancer. However, after receiving the vaccine, many women may no longer feel the need to follow a regular screening schedule or may incorrectly understand the vaccine as a shield against all types of sexually transmitted diseases. The possibility of this potentially dangerous sense of invincibility has led to a twin fear of missed Pap tests and riskier sexual behavior. As an article in the *New England Journal of Medicine* cautions, “vaccination against

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77. Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1560 (2002).

78. For example, debates rage over how much money should be spent on the last months of one’s life and whether those without financial resources have a right to organ transplantation.

79. Homan, *supra* note 24, at 210.

HPV may . . . alter sexual behavior in the population or lead to a misperception that screening is no longer necessary.”<sup>80</sup> These fears resonate with some religious groups. For example, an article published in *Catholic Medical Weekly* warned that although the vaccine does not offer complete protection, “it’s easy to imagine a 12 year old . . . who thinks it does.”<sup>81</sup> Thus, economic modeling of HPV vaccination must deal with the very real possibility of women failing to comply with a regular screening schedule or engaging in more high-risk sexual activity.

If these fears are confirmed and vaccination leads to riskier behavior and lower compliance with recommended cervical cancer screening, women who receive the vaccine may eventually require more medical care than those who remain unvaccinated.<sup>82</sup> This paradoxical increase in long-term health care costs would dramatically alter a cost-effectiveness analysis of mandatory vaccination. Therefore, it is essential that any economic model address this potentially deleterious effect of vaccination before proclaiming that mandatory vaccination is economically sound.

Next, the long-term health effects of the HPV vaccine itself are not yet fully known. As of June 2012, approximately forty-six million doses of HPV vaccine were distributed in the United States, and the Vaccine Adverse Event Reporting System (VAERS) received a total of 20,096 reports of adverse events following vaccination.<sup>83</sup> Of the total number of VAERS reports regarding Gardasil, 8% were considered serious, which is defined as “an event resulting in [d]eath, [I]ife-threatening illness, [h]ospitalization, [p]rolongation of existing hospitalization [or

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80. Jane J. Kim & Sue J. Goldie, *Health and Economic Implications of HPV Vaccination in the United States*, 359 *NEW ENG. J. MED.* 821, 829 (2008); see also Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 *J.L. MED. & ETHICS* 384, 388 (2008) (raising concerns about “a negative impact of vaccination on cervical cancer screening programs, which are highly effective at reducing cervical cancer mortality”); Shalini L. Kulasingam & Evan R. Myers, *Potential Health and Economic Impact of Adding a Human Papillomavirus Vaccine to Screening Programs*, 290 *J. AM. MED. ASS’N* 781, 788 (2003) (voicing concerns even before the FDA approved the vaccine that women who are vaccinated may feel protected and not participate in screening programs).

81. Collins, *supra* note 22.

82. Evan Myers et al., *The Current and Future Role of Screening in the Era of HPV Vaccination*, 109 *GYNECOL. ONCOLOGY* S31, S35 (2008) (suggesting that “if vaccinated women are less likely to adhere to screening recommendations because of a belief of complete cervical cancer protection, outcomes could actually worsen”).

83. *HPV Vaccine Information for Clinicians—Fact Sheet*, *CTRS. FOR DISEASE CONTROL & PREVENTION*, <http://www.cdc.gov/std/hpv/stdfact-hpv-vaccine-hcp.htm> (last updated July 12, 2012).

p]ersistent or significant disability.”<sup>84</sup> How strongly linked vaccination administration was to these serious events remains unknown. What is known is that the vaccine has been on the market for less than a decade, and the first generation of targeted eleven- and twelve-year-old girls who received the vaccine have not yet reached their reproductive peak. As such, the full impact of the HPV vaccine will not be observable for many years and, therefore, “decisions regarding a vaccination policy will inevitably [need to] rely on studies reporting intermediate outcomes.”<sup>85</sup> Unfortunately, the current reality is that we do not know the extent or magnitude of the negative effects associated with the vaccine.<sup>86</sup> Whether the vaccine will lead to more serious and unpredicted adverse events in the future is an unanswered question. Thus, an economic model regarding HPV vaccination must attempt to address the many lingering questions regarding the safety of the vaccine, and adequately account for short- and long-term health effects.

Similarly, the duration of action of the HPV vaccine, designated as one of “the most important variable[s]” in determining the vaccine’s impact, also remains an unanswered question.<sup>87</sup> If the vaccine’s protection fades away after several years and additional shots are necessary, the total cost of administering the vaccine increases without a proportional decrease in the cost of treating cervical cancer and other HPV-related complications in the future. As such, economic modeling of HPV vaccination must deal with the current uncertainty regarding duration of action. To date, some mathematical models assume vaccine efficacy lasting ten years then declining to zero without booster

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84. *Id.* Gardasil has also been loosely linked to fifty-three deaths worldwide. See Hud, *supra* note 5, at 230.

85. Kim & Goldie, *supra* note 80, at 822.

86. Javitt et al., *supra* note 80, at 387–88. Given the uncertainty about adverse effects and long-term efficacy, doubts have been raised about competing agendas (e.g. profit motive for the pharmaceutical companies involved). One author gave voice to these concerns:

When weighing evidence about risks and benefits, it is also appropriate to ask who takes the risk, and who gets the benefit. Patients and the public logically expect that only medical and scientific evidence is put on the balance. If other matters weigh in . . . the balance is easily skewed.

Charlotte Haug, *The Risks and Benefits of HPV Vaccination*, 302 J. AM. MED. ASS’N 795, 796 (2009).

87. Sarah Jeurissen & Amin Makar, *Epidemiological and Economic Impact of Human Papillomavirus Vaccines*, 19 INT’L J. GYNECOL. CANCER 761, 764 (2009).

shots,<sup>88</sup> while others assume lifelong efficacy—assumptions which dramatically affect the predicted cost-benefit ratios.<sup>89</sup>

Economic models must also draw a distinction between cost-effectiveness and affordability. Medical interventions with high value are often times not affordable for a significant population.<sup>90</sup> Gardasil is one of the most expensive vaccines ever developed.<sup>91</sup> Each dose in the three-dose series costs \$120, totaling \$360 for the complete vaccine package. Some private and public sector payers cover the cost of the vaccine, but “policies vary regarding the age of the coverage, the reimbursement levels paid by different payers, and the out-of-pocket costs faced by health care consumers.”<sup>92</sup> This variable insurance coverage coupled with the vaccine’s cost has the potential to impose significant financial strain on families. It is therefore crucial to acknowledge that even if mandatory vaccination is cost-effective on a national level, it still may be an economic hardship for individuals. Thus, while the vaccine may arguably be cost-effective, it is certainly not inexpensive and, for this reason, it may not be the most efficient or attractive health care step for many families to take.<sup>93</sup>

The problem of affordability also raises the question of who should pay for the vaccine. Should insurance companies be forced to cover it? Should low-income families be exempt from the mandate? Should the federal government cover the cost? There is often a tendency to evaluate single diseases or particular interventions in isolation and fail to understand how they fit into

88. Kulasingam & Myers, *supra* note 80, at 787.

89. Win Techakehakij & Roger D. Feldman, *Cost-Effectiveness of HPV Vaccination Compared with Pap Smear Screening on a National Scale: A Literature Review*, 26 *VACCINE* 6258, 6261 (2008).

90. Jane J. Kim, *The Role of Cost-Effectiveness in U.S. Vaccination Policy*, 365 *NEW ENG. J. MED.* 1760, 1760 (2011).

91. Homan, *supra* note 24, at 196.

92. *HPV Vaccine*, *supra* note 11.

93. *But see* Hud, *supra* note 5. Recognizing the financial burden felt by some families, the federal government provides free vaccination for children up to age eighteen who are Medicaid eligible and uninsured in its Vaccine for Children Program. Additionally, as Dr. Deborah Arrindell, Vice-President of Health Policy at The American Social Health Organization states, “[m]iddle school may be the last public health gate we all walk through together, before kids begin dropping out of schools or get a crummy job without health insurance, or enter the workforce in general with its fragmented healthcare system.” *Id.* at 246–47 (quoting Karen Houppert, *Who’s Afraid of Gardasil?*, *THE NATION*, Mar. 8, 2007, at 5). For this reason, the high price tag of the vaccine is arguably offset. Interestingly, Merck also created its own program designed to provide Gardasil to individuals falling below 200 percent of the national poverty line.

a broader picture.<sup>94</sup> Thus, while individual vaccines may appear cost-effective, the “overall U.S. vaccination program may be unaffordable or provide less value than other bundled preventive health services targeting the same age group.”<sup>95</sup> The issue of affordability also highlights that cost-effectiveness models need to consider the role that healthcare access and health disparities will play. How will vaccination and screening vary for different populations and different communities? Bridging the gap between cost-effectiveness and affordability is another challenging task an economic approach must address.

Finally, a multitude of other variables must be dealt with, including: the possibility of cross-protection against other types of HPV;<sup>96</sup> the phenomenon of “herd immunity”;<sup>97</sup> vaccine efficacy;<sup>98</sup> the percentage of girls and women predicted to be vaccinated;<sup>99</sup> the age of onset and frequency of Pap smear screening recommended;<sup>100</sup> predicted compliance with screening, follow-up, and treatment;<sup>101</sup> how costs are calculated (e.g. whether or not to include indirect expenses);<sup>102</sup> outcome parameters (e.g. whether or not to include the benefits of preventing HPV-related non-cervical cancers or genital warts);<sup>103</sup> and whether a discount rate is included in the analysis (a discount rate adjusts for the fact that individuals prefer to receive benefits sooner rather than

94. See, e.g., Javitt et al., *supra* note 80, at 392. The potential consequences of a mandated vaccine are varied. For example, these authors suggest “[a]dding HPV could drive more states to abandon funding for other vaccinations and could divert funding from other important public health measures.” *Id.* They note that even physicians have argued that “the rising costs of vaccines and the rising number of new mandatory vaccines make it increasingly difficult for them to purchase vaccinations initially and that they net a loss due to insufficient reimbursement from insurers.” *Id.* at 392–93.

95. Kim, *supra* note 90, at 1761.

96. See Kim & Goldie, *supra* note 80, at 826.

97. See Chesson et al., *supra* note 3, at 246.

98. See Tjalke A. Westra et al., *Until Which Age Should Women Be Vaccinated Against HPV Infection? Recommendation Based on Cost-Effectiveness Analyses*, 204 J. INFECTIOUS DISEASES 377, 379 (2011).

99. See Kulasingam & Myers, *supra* note 80, at 782. Some studies assume 100% coverage, while others assume increasing rates, then stabilizing at 70%. See Techakehakij & Feldman, *supra* note 89, at 6260.

100. See *id.*

101. Jaume Puig-Junoy & Beatriz G. Lopez-Valcarcel, *Economic Evaluations of Massive HPV Vaccination: Within-Study and Between Study Variations in Incremental Cost Per QALY Gained*, 48 PREVENTIVE MED. 444, 445 (2009).

102. See Westra et al., *supra* note 98, at 379.

103. See Fawziah Marra et al., *Effectiveness and Cost Effectiveness of Human Papillomavirus Vaccine: A Systematic Review*, 27 PHARMACOECONOMICS 127, 144 (2009).

later and incur costs later rather than sooner).<sup>104</sup> Modeling needs to consider these and other variables, decide whether or not they should be included in the analysis, and make assumptions regarding those variables included, with little definitive data backing up the assumptions made.

In short, the HPV vaccine is just too new to fully understand all of its ramifications, both positive and negative. As discussed, many questions remain including the effects of HPV vaccination on regular screening, unforeseen health consequences that may arise over time, duration of protection, vaccine affordability, achievable coverage rates, and the equitability of coverage.<sup>105</sup> Given the impressive number of variables and the current uncertainties about which values to assign for each, the assumptions underlying each of the many existing mathematical models have a profound influence on their conclusions.<sup>106</sup> However, in spite of all of the unknowns that seriously compromise the accuracy and usefulness of these predictions, these formal approaches to analyzing cost-effectiveness have an important role to play in shaping public policy and legal discussions.<sup>107</sup> Rigorous work has already been devoted to determining the economic impact of different strategies related to the prevention of HPV-related disease.<sup>108</sup> As the HPV vaccine continues to reach a larger population and as these analyses become increasingly sophisticated and accurate, courts and legislatures will need to remain aware of the information and insights these models provide.

### B. *Exploring the Cost-Effectiveness of HPV Vaccination*

Legislation mandating certain vaccinations is driven by myriad factors, including “vaccine safety and efficacy, avertable dis-

104. Puig-Junoy & Lopez-Valcarcel, *supra* note 101, at 445.

105. For a sophisticated analysis of these “parameter uncertainties” that may cause variations in cost per QALY gained, see Puig-Junoy & Lopez-Valcarcel, *supra* note 101.

106. See Jeurissen & Makar, *supra* note 87, at 761 (stating that cost-effectiveness ratios are extremely varied and highly dependent on assumptions made).

107. See Marra et al., *supra* note 103, at 143 (suggesting that mathematical modeling and economic analyses provide important data for policy decisions).

108. See, e.g., Marc Brisson et al., *Economic Evaluation of Human Papillomavirus Vaccination in Developed Countries*, 12 PUB. HEALTH GENOMICS 343 (2009). Although many economic studies are producing consistent conclusions that vaccinating young girls against HPV is likely to be cost-effective, myriad challenges remain to be addressed, including the difficulty of measuring simultaneously the impact of different prevention strategies such as conventional screening and vaccination. *Id.* at 345.

ease burden, acceptability, and societal value.”<sup>109</sup> The cost-effectiveness of a particular vaccination program is an additional factor, and one with perhaps the greatest potential to shape future healthcare policy. A cost-effectiveness analysis “provides information on whether the health gain associated with each new vaccine is worth the cost, as compared with other options for health spending.”<sup>110</sup> In general, a cost-effective vaccine has low cost, high efficacy, and results in a situation in which “the up-front expenditure for vaccination is entirely offset by costs averted through disease prevention.”<sup>111</sup> According to this view, to be considered cost-effective, the expected cost of administering the HPV vaccine nationwide to school-age girls must be less than the cost of treating cervical cancer and other HPV-related diseases.<sup>112</sup> Fortunately, as discussed below, this is not the prevailing view, which instead factors the health benefits of a particular intervention into the equation. The prevailing view is that some achievable health benefits—for example, improved quality of life and/or longer life expectancy—are worth paying for as long as the incremental cost is below an agreed-upon threshold.

Many recent studies argue that widespread administration of the HPV vaccine is a cost-effective strategy. According to research presented in the *New England Journal of Medicine*, the HPV vaccination is expected to be “economically attractive . . . if high coverage can be achieved in the primary target group of 12-year-old girls . . . .”<sup>113</sup> Similarly, a study presented in the *International Journal of Gynecological Cancer* suggests that the HPV vaccine can be cost-effective so long as the duration of vaccine-related immunity is high, efficacy is high, price is low, and the vaccine is administered before the onset of sexual activity.<sup>114</sup> Regarding

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109. Kim, *supra* note 90, at 1760.

110. *Id.* at 1761.

111. *Id.* at 1760.

112. In other words, in order for something to be cost-effective, it must be efficacious and come at a reasonable price. What constitutes a reasonable price will be decided by what society determines is reasonable. For example, a \$50,000 lifetime incremental expense for each quality-adjusted year of life gained by vaccinated women may be considered cost-effective.

113. Kim & Goldie, *supra* note 80, at 827. Although mandatory vaccination of school-age boys is beyond the scope of this Note, it is worth mentioning that the results of at least one study found that “vaccinating boys will most likely not be cost-effective in countries that can reach high coverage rates in girls.” See Brisson et al., *supra* note 108, at 350.

114. Jeurissen & Makar, *supra* note 87, at 761; see also Marra et al., *supra* note 103, at 144–45 (showing that systematic review of the literature has revealed that a female-only vaccination program added to regular screening is cost-effective compared with the cytology-based Pap smear screening alone. All models showed that the HPV vaccine in females may be considered cost-effec-

the cost of administering the vaccine, the three-dose series costs a total of \$360, plus the cost of wastage and supplies. Included within the vaccine administration cost is the vaccine price and delivery program costs. The cost of treating cervical cancer nationwide, on the other hand, ranges from \$300 to \$400 million annually, which includes “direct medical costs associated with screening, diagnosis, and treatment (such as tests, procedures, and hospitalizations) . . . .”<sup>115</sup>

An acceptable method of evaluating the potential cost-effectiveness of a particular strategy like HPV vaccination relies on what is known as a “QALY” measurement, the incremental cost per quality-adjusted life year gained.<sup>116</sup> QALY is a “metric for health and longevity that is now widely used by health economists, public health scholars, and others researching the economics of health care,”<sup>117</sup> and takes into account measures of disease burden on the “quality and quantity of life lived.”<sup>118</sup> Some have suggested that a strategy may be considered cost-effective in the United States if the incremental cost-effectiveness ratio is in the range of \$50,000–80,000 per QALY saved.<sup>119</sup> In

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tive because it produces a cost per QALY ratio below a traditionally used cut-off of \$50,000 per QALY.); Kulasingam & Myers, *supra* note 80, at 781 (“Vaccination plus biennial screening delayed until age 24 had the most attractive cost-effectiveness ratio (\$44,889) compared with screening only beginning at 18 years and conducted every three years. However, the strategy of vaccination with annual screening beginning at age 18 had the largest overall reduction in cancer incidence and mortality at a cost of \$236,250 per life-year gained compared with vaccination and annual screening beginning at age 22 years.”).

115. Jane J. Kim et al., *Cost-Effectiveness of Human Papillomavirus Vaccination and Cervical Cancer Screening in Women Older Than 30 Years in the United States*, 151 ANNALS INTERNAL MED. 538, 540–41 (2009).

116. One such study developed a model to estimate the cost-effectiveness (cost per QALY) of adding HPV vaccination of twelve-year-old girls to existing cervical cancer screening practices. The study included all direct medical costs and benefits regardless of who incurred the costs or received the benefits. Results indicated an estimated cost per QALY gained of \$3906–\$14,723 depending on a variety of factors. However, the analysis did not address all of the potential costs and benefits, including cross-protection against high-risk types of HPV other than sixteen and eighteen and prevention of other cancers. See Chesson et al., *supra* note 3, at 249.

117. Matthew D. Adler, *QALYs and Policy Evaluation: A New Perspective*, 6 YALE J. HEALTH POL’Y L. & ETHICS 1, 1 (2006).

118. Homan, *supra* note 24, at 197.

119. Myers et al., *supra* note 82, at S33. The oft-quoted acceptable range of \$50,000–\$80,000 per QALY is decades old, not evidence-based, and it is unclear what this value range is today (higher and lower ranges have been suggested). A recent study, however, confirms that the range quoted above remains reasonable in today’s market and further notes: “Making decisions that consider cost effectiveness . . . of healthcare interventions has become increasingly important.” Takeru Shirowa et al., *International Survey on Willingness-to-Pay*

studies comparing the cost-effectiveness of an HPV vaccination program plus regular Pap screening with Pap screening alone, the range of cost-effectiveness ratios turned out to be between \$16,600 and \$27,231 per QALY gained.<sup>120</sup> As women age, however, the cost-effectiveness of the vaccine diminishes. One study found that “as the age at vaccination increased so did the cost per QALY gained.”<sup>121</sup> For example, while the cost-effectiveness ratio for twelve-year-old girls was \$43,600 per QALY, the ratio was \$120,400 per QALY for twenty-one-year-old girls, and \$152,700 for twenty-six-year-old women.<sup>122</sup> This type of analysis, of course, raises an important and difficult ethical issue: the incidence of cervical cancer, and its effect on quality of life and life expectancy, can be lessened by initiating Pap screening earlier and more frequently than currently recommended and by offering “catch-up” vaccination to women older than eighteen years old; however, this comes at substantial cost. How much is a “quality-adjusted life year” actually worth to United States citizens? Thus far, a cost-effectiveness analysis has been used in the public health policy arena in the United States on a very limited basis, in contrast to countries such as Australia, Great Britain, Canada, and New Zealand, “which now regularly evaluate cost-effectiveness of pharmaceuticals or health technologies proposed for public reimbursement.”<sup>123</sup> As noted, unlike some other countries, the United States has not agreed upon a cost-effectiveness threshold for health-related interventions.<sup>124</sup>

In sum, a large amount of money, time, and brainpower are currently being expended on QALY research and that research promises to play an important role in shaping health policy. Given the growing financial pressures that many countries face today and will continue to face in the future, this type of economic approach is likely to increasingly influence public policy and legislation.<sup>125</sup> In light of the many variables and uncertain-

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(WTP) for One Additional QALY Gained: What Is the Threshold of Cost Effectiveness?, 19 HEALTH ECON. 422, 435 (2010).

120. See Techakehakij & Feldman, *supra* note 89, at 6260–63. The studies assumed that the duration of protection with the vaccine ranged from ten years to a lifetime. *Id.* at 6260.

121. T.C. Pomfret et al., *Quadrivalent Human Papillomavirus (HPV) Vaccine: A Review of Safety, Efficacy, and Pharmacoeconomics*, 36 J. CLINICAL PHARMACY & THERAPEUTICS 1, 6 (2011).

122. *Id.*

123. Adler, *supra* note 117, at 4.

124. Kim, *supra* note 115, at 543.

125. Cost-effectiveness analysis is also important for medical societies responsible for developing guidelines for screening and vaccination, as these guidelines take cost into account.

ties involved, the approach does not yet appear ready for implementation; however, even in its current imprecise form, the approach is able to provide valuable insights about the relative cost-benefit ratios of different strategies. Although in its infancy, cost-effectiveness modeling in HPV programs and numerous other healthcare initiatives is something to be aware of. An economic approach will undoubtedly expand in influence in the years to come and affect laws and policies regarding HPV vaccination.

Designed to influence social policy, a purely economic approach is flawed and raises more questions than perhaps it answers. As the use of cost-effectiveness analyses increases, it is imperative that limitations of the approach be acknowledged and addressed. An article in *Preventive Medicine* succinctly described the benefits and limitations of economic modeling:

Economic evaluation models are increasingly sophisticated. They fit all relevant epidemiologic and economic data into a set of up to dozens of thousands of plausible scenarios. But omni-comprehension of those alternative worlds created by the modeler in order to give thorough scientific treatment to epidemiologic and market uncertainty does not compensate for the lack of basic information. Those models are useful for policy purposes only to the extent they can reduce uncertainty.<sup>126</sup>

However, despite its shortcomings, cost-effectiveness modeling will become more sophisticated and accurate, and will be increasingly used by politicians, legislatures, and medical societies in the future.<sup>127</sup> As such, it behooves lawyers to be aware of this type of analysis—its strengths, flaws, and its probable expanding role in future laws and decision-making. As we have learned from Judge Posner, economic considerations should become a part of our discussions and planning regarding law, ethics, and public policy.

#### IV. CONCLUSION

Transmitted exclusively through sexual activity, HPV is markedly different from other types of diseases that have led to mandatory vaccinations in the past. Given HPV's prevalence in

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126. Puig-Junoy & Lopez-Valcarcel, *supra* note 101, at 446 (citation omitted).

127. *See, e.g., id.* (acknowledging the increasing sophistication of economic evaluation models regarding the HPV vaccine, but also recognizing that there remain significant variations in cost per QALY estimates of vaccination programs around the world).

society and potentially fatal consequences, Merck's development of the HPV vaccine, Gardasil, was revolutionary. With the introduction of the vaccine came highly publicized controversy over its safety and appropriateness. As states began considering a mandatory HPV vaccination program for school-age girls, the debates intensified, and opponents drew arguments from legal, religious, and philosophical grounds.

Those against a mandatory vaccine argue that requiring HPV inoculation represents an encroachment on parental autonomy as well as an excessive exercise of state police power. As HPV-related diseases can be prevented through other, less intrusive, means such as Pap tests and modified sexual behavior, mandating the vaccine can be seen as an affront to individual liberty. Also, requiring young girls to receive a vaccine that protects against a sexually transmitted infection has the same effect, some argue, as expressly encouraging promiscuity. Add in the enormous profit Merck, a company criticized for its lack of transparency and excessive lobbying, stands to make from widespread implementation, and mandatory vaccination can then be viewed as an unwise strategy.

On the other side, proponents insist that mandatory HPV vaccination falls squarely within a state's police power as defined by Supreme Court precedent. A parent's right to privacy is not absolute, they argue, and in certain serious circumstances concern for the common good trumps individual liberty interests. Moreover, compulsory HPV vaccination aligns with the current reality of increased sexual activity among young girls.

Although mandatory HPV vaccination for school-age girls might be implemented in several states in the near future, the amount of unanswered questions about the safety and efficacy of the vaccine demand a more cautious approach. High quality, unbiased research needs to be done in order to learn even more about the vaccine, and as the debates surrounding the vaccine continue, states will ideally take the lead in treating HPV in the same way as other communicable diseases have been dealt with in the past.

Mathematical models that attempt to determine the economic impact of certain public health strategies will contribute to the debate in a substantial way as these models become increasingly accurate and sophisticated. These models are currently imprecise, as they are forced to account for a range of variables of unknown value, including the duration of protection of the vaccine, the vaccine's efficacy, effects of the vaccine on sexual behavior, unequal coverage of populations at risk, and any long-term health effects of the vaccine. Yet, they have the potential to

significantly influence public policy and legal discourse as the United States determines how best to use a finite amount of resources. Becoming familiar with the insights provided by cost-effectiveness analyses of HPV vaccination programs will enable those in the legal, public policy, and political arenas to have a more thorough understanding of this ongoing debate, which will continue for many more years.

