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## DISPATCH FROM THE CULTURE WAR: VIRGINIA'S FAILED HPV VACCINATION MANDATE

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### INTRODUCTION

In 2007, Virginia leapt ahead of her sister states, passing a law to mandate the Gardasil HPV vaccine for all females entering the sixth grade.<sup>1</sup> Washington, D.C. followed suit, and Texas Governor Rick Perry attempted to effect a requirement by executive order, though it was overridden by the state legislature.<sup>2</sup> In the intervening five years, nineteen other states have passed laws establishing commissions to study the use of Gardasil, requiring Medicaid to pay for the vaccine, or establishing—and sometimes even appropriating funds to pay for—other state agency programs to offer the vaccine at no charge.<sup>3</sup> No other state, however, has passed a Gardasil vaccination requirement.<sup>4</sup>

Gardasil protects those vaccinated from strains of the sexually transmitted HPV virus that cause cervical cancers.<sup>5</sup> Critics of the vaccine suggest that adolescents and teenagers given such protection will assume that the vaccination confers upon them society's approval of and permission to engage in premarital sex.<sup>6</sup> Some also oppose the vaccine, decrying its safety record.<sup>7</sup> Vaccine supporters from the health care community protest that

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<sup>1</sup> See VA. CODE ANN. § 32.1-46 (2011).

<sup>2</sup> *HPV Vaccine*, NATIONAL CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified Apr. 2012).

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

<sup>4</sup> See *id.* (detailing state-by-state legislation relating to HPV vaccination).

<sup>5</sup> Remarks of Dr. Anne Schuchat, Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention, (June 26, 2006), available at <http://www.cdc.gov/media/transcripts/t060629.htm>.

<sup>6</sup> Michael Gerson, *A Dose of Reality for the HPV Debate*, WASH. POST, Sept. 15, 2011, available at [http://www.washingtonpost.com/opinions/a-dose-of-reality-for-the-hpv-debate/2011/09/15/gIQAd2EfVK\\_story.html](http://www.washingtonpost.com/opinions/a-dose-of-reality-for-the-hpv-debate/2011/09/15/gIQAd2EfVK_story.html).

<sup>7</sup> Matthew Herper, *The Gardasil Problem: How The U.S. Lost Faith In A Promising Vaccine*, FORBES, Apr. 4, 2012, available at <http://www.forbes.com/sites/matthewherper/2012/04/04/americas-gardasil->

HPV, like any other communicable disease, requires blanket herd immunity to be defeated, and that personal choice is irrelevant.<sup>8</sup> Additionally, women's rights groups suggest that much of the opposition derives from a desire to punish women for premarital sex.<sup>9</sup>

In four of the last five legislative sessions, members of the Virginia General Assembly have tried to repeal the mandate.<sup>10</sup> In their 2012 attempt, they came very close to succeeding.<sup>11</sup> The bill was ultimately left in committee in the Senate, but the relative success achieved by supporters of the mandate's repeal is noteworthy.<sup>12</sup> During the political campaigns of 2011, Texas Governor Rick Perry's executive order brought the issue of a state mandate for the vaccine to the national attention.<sup>13</sup> Fellow candidate Michele Bachmann criticized Perry for subjecting young girls to a vaccine that allegedly subverts the purpose of abstinence, and even suggested that Gardasil posed health risks including mental retardation and death.<sup>14</sup> While the latter criticism does not hold water, Bachman's passionate condemnation of government mandated STD prevention has proven more galvanizing.<sup>15</sup> The issue appears to have devolved into another chapter in the culture wars, and the question of how HPV vaccination laws have affected actual coverage seems to have become overshadowed.

This paper will inquire into what makes Gardasil different from other vaccines, and how that impacts its administration. Part I will describe the specifics of the HPV vaccine: how it works and how Virginia decided to promote its usage. Part II will examine the ways in which jurisdictions have traditionally understood vaccination policy, and contrast it with the ways in which they have handled the HPV vaccine. Part III will examine the disadvantages of continuing the mandate's ineffective political war of attrition, and suggest a coalition-building strategy to effect policy that honors communal values and meaningfully increases access to the vaccine.

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<sup>8</sup> *Id.*

<sup>9</sup> Nancy Gibbs, *Defusing the War Over the "Promiscuity" Vaccine*, TIME, June 21, 2006, available at <http://www.time.com/time/nation/article/0,8599,1206813,00.html>.

<sup>10</sup> *HPV Vaccine*, NCSL.ORG, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified June 2012).

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

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

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

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

<sup>15</sup> *Id.*

## I. THE HPV VACCINE

## A. HPV Basics

Though it only recently emerged as an issue of national concern,<sup>16</sup> genital human papillomavirus, or “HPV,” is the most common sexually transmitted infection in the United States.<sup>17</sup> Of the twenty million people currently infected with HPV in the United States,<sup>18</sup> 90% will experience no symptoms, and the virus will run its course within approximately two years.<sup>19</sup> The remaining 10% will experience different symptoms, depending on the type of strain involved.<sup>20</sup> These symptoms range from genital warts, warts in the throat, and cervical and other<sup>21</sup> cancers.<sup>22</sup> HPV spreads easily because it is transmitted by skin-to-skin contact, instead of an exchange of bodily fluids, and because many who are infected are asymptomatic and thus unaware of their infection.<sup>23</sup> Though medical awareness of the link between HPV and cervical cancer was relatively low until the most recent decade,<sup>24</sup> the National Institutes of Health approximates that HPV is responsible for approximately 70% of the twelve thousand cases of cervical cancer diagnosed each year in the United States.<sup>25</sup> Approximately four thousand women die every year from cervical cancer in the United States.<sup>26</sup>

## B. A Vaccine for Cancer

On June 16, 2006, the Food and Drug Administration approved Merck Pharmaceuticals’ vaccine for HPV, called “Gardasil,” for use in girls aged nine to twenty-six.<sup>27</sup> No ordinary immunization, Gardasil promised what

<sup>16</sup> Stephanie Stapleton, *More Awareness of HPV's Role Urged*, AM. MED. NEWS, Feb. 28, 2000, <http://www.ama-assn.org/amednews/2000/02/28/hlsc0228.htm>.

<sup>17</sup> *Genital HPV Infection - Fact Sheet*, CENTERS FOR DISEASE CONTROL, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last modified Feb. 15, 2012).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

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

<sup>21</sup> *Id.* (These include “cancers of the vulva, vagina, penis, anus, and oropharynx (back of throat including base of tongue and tonsils)”).

<sup>22</sup> *Genital HPV Infection - Fact Sheet*, CDC, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last modified Feb. 15, 2012).

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

<sup>24</sup> Stapleton, *supra* note 17.

<sup>25</sup> *HPV and Cancer*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/HPV> (last visited Apr. 29, 2012).

<sup>26</sup> *Cervical Cancer Statistics*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/cancer/cervical/statistics/> (last modified Nov. 23, 2010).

<sup>27</sup> *FDA Approves First Vaccine for Cervical Cancer*, MSNBC, June 16, 2006, <http://www.msnbc.msn.com/id/13206572/ns/health-cancer/#.T5yYgMRYSrD>.

had previously been only a fantasy for the medical profession: a vaccine that would protect against cancer.<sup>28</sup> Specifically, the vaccine protects recipients from the two strains of HPV—16 and 18— that cause cervical cancers.<sup>29</sup> Though no long-term data is available, studies have demonstrated that the vaccine is 98.5% effective for at least five years, and likely longer.<sup>30</sup> Gardasil is also the most expensive vaccination to ever gain FDA approval, at a total cost of \$360, or \$120 for each of the three shots required over a period of six months.<sup>31</sup> Approximately 26.7% of girls between the ages of thirteen and seventeen have been fully vaccinated (with all three shots) in the last five years,<sup>32</sup> and just 1% of boys has been vaccinated even though the vaccine has been FDA-approved for use in boys for nearly three years.<sup>33</sup>

Two weeks after Gardasil's FDA approval, the Centers for Disease Control and Prevention (CDC) recommended that adolescent girls between eleven and twelve years of age be vaccinated.<sup>34</sup> During the press conference announcing its decision, the Advisory Committee on Immunization Practices (ACIP) spokeswoman Dr. Anne Schuchat commented,

You know, I think this is an incredible opportunity for parents and an incredible opportunity for our country. This is a cancer prevention vaccine. It also turns out to prevent the most common sexually transmitted infection in the country. And this is a great opportunity for us to make advances in prevention."<sup>35</sup>

Dr. Schuchat explicitly addressed the committee's decision to advocate that states inoculate girls before the age of sexual maturity, giving two reasons to target this particular age group. First, she explained that because vaccines only work before exposure to the virus, it makes sense to inoculate girls before they begin sexual activity.<sup>36</sup> Second, she noted that young teens

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<sup>28</sup> *HPV Vaccination of Women Aged 16–26 in Virginia*, DIVISION OF LEGISLATIVE AUTOMATED SYSTEMS, Sept. 19, 2007, available at [http://services.dlas.virginia.gov/user\\_db/frmjchc.aspx?viewid=582](http://services.dlas.virginia.gov/user_db/frmjchc.aspx?viewid=582) [hereinafter *HPV Vaccination of Women*].

<sup>29</sup> Remarks of Dr. Anne Schuchat, Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention, Oct. 25, 2011, available at [http://www.cdc.gov/media/releases/2011/t1025\\_hpv\\_12yroldvaccine.html](http://www.cdc.gov/media/releases/2011/t1025_hpv_12yroldvaccine.html).

<sup>30</sup> Rebecca Gudeman, *High Cost of HPV Vaccine Limits Use in Surprising Way*, YOUTH L. NEWS, Apr. 2007, available at [http://www.youthlaw.org/publications/yln/2007/april\\_june\\_2007/high\\_cost\\_of\\_hpv\\_vaccine\\_limits\\_use\\_in\\_surprising\\_way/](http://www.youthlaw.org/publications/yln/2007/april_june_2007/high_cost_of_hpv_vaccine_limits_use_in_surprising_way/).

<sup>31</sup> Richard Knox, *Why HPV Vaccination of Boys May Be Easier*, NPR, Nov. 7, 2011, <http://www.npr.org/blogs/health/2011/11/07/142030282/why-hpv-vaccination-of-boys-may-be-easier>.

<sup>32</sup> Centers for Disease Control and Prevention, *National, State, Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years-U.S. 2009*, MORBIDITY AND MORTALITY WEEKLY REPORT, Aug. 20, 2010, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5932a3.htm>.

<sup>33</sup> Knox, *supra* note 32.

<sup>34</sup> Remarks of Dr. Anne Schuchat, *supra* note 30.

<sup>35</sup> Remarks of Dr. Anne Schuchat, *supra* note 6.

<sup>36</sup> *Id.* See Gardiner Harris, *Panel Endorses HPV Vaccine for Boys of 11*, N.Y. TIMES, Oct. 25, 2011,

have a much higher vaccine antibody response than older teens or adult women, making it more effective at the recommended age.<sup>37</sup> The committee also addressed the notion of herd, or community immunity, as an element of their attempt to propose a recommendation with the highest possible level of effectiveness.<sup>38</sup> In October 2011, ACIP released a recommendation that all boys aged eleven to twelve also receive a vaccination for HPV, citing the same reasons used four years previously.<sup>39</sup>

Though some anti-vaccine groups have questioned Gardasil's safety, there have been no statistically significant complications from the vaccine in five years.<sup>40</sup> Concerns that girls have developed conditions like Guillain-Barre Syndrome after vaccination do not take into account that there is an expected number of people within the general population who will get a particular disease, and sometimes vaccination and illness happen with close temporal proximity.<sup>41</sup> Reports that Gardasil causes mental retardation have no basis in scientific fact.<sup>42</sup>

### C. The Virginia Approach

Once the CDC made their recommendation, the Commonwealth of Virginia responded immediately. In the following legislative session, the General Assembly amended its compulsory school vaccination statute to require “[t]hree doses of properly spaced human papillomavirus (HPV) vaccine for females. The first dose shall be administered before the child enters the sixth grade.”<sup>43</sup> However, the law contains an exemption provision: “A parent or guardian, at the parent or guardian’s sole discretion, may elect for their child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus

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[http://www.nytimes.com/2011/10/26/health/policy/26vaccine.html?\\_r=1](http://www.nytimes.com/2011/10/26/health/policy/26vaccine.html?_r=1) (“More than one in five boys and girls have had vaginal sex by the age of 15, surveys show”).

<sup>37</sup> Remarks of Dr. Anne Schuchat, *supra* note 6.

<sup>38</sup> *Id.* For an explanation of “herd immunity,” see footnotes 54–57, *infra*, and accompanying text.

<sup>39</sup> Remarks of Dr. Anne Schuchat, *supra* note 6.

<sup>40</sup> Christina O. Hud, *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, 230–31 (2010).

<sup>41</sup> *Id.*

<sup>42</sup> Matthew Herper, *The Gardasil Problem: How The U.S. Lost Faith In A Promising Vaccine*, FORBES, Apr. 4, 2012, <http://www.forbes.com/sites/matthewherper/2012/04/04/americas-gardasil-problem-how-politics-poisons-public-health/> (“Otis Brawley, chief medical officer of the American Cancer Society, calls the episode ‘disastrous.’ ‘It’s an insult that people are not looking at the evidence,’ says Brawley. ‘It’s a tragedy that we could prevent people from dying from cervical and head and neck cancer but our society just can’t bring itself to have an open, rational, scientific discussion about the facts.’”).

<sup>43</sup> VA. CODE ANN. § 32.1-46 (2011).

and cervical cancer approved for such use by the Board.”<sup>44</sup> The statutory language explicitly sets the vaccine apart from the others on the list, explaining that this is “[b]ecause the human papillomavirus is not communicable in a school setting.”<sup>45</sup>

Five years later, Virginia’s coverage rate is 41.5%, which is nine percentage points higher than the national average (32%), but fourteen percentage points lower than Rhode Island, the state with the highest coverage (55.1%).<sup>46</sup> Because very little time passed between the availability of the vaccine and the mandate, there is no way to measure the mandate’s effect in the Commonwealth against prior vaccination levels, but it is clear that the mandate is responsible for a higher level of coverage: “[d]uring the last fiscal year, health departments throughout Virginia administered 6,479 doses to sixth-grade girls. About 4,000 were paid for through the federal Vaccines for Children program, which will continue even without a mandate.”<sup>47</sup> Furthermore, “[i]n Virginia’s eastern region, which includes Hampton Roads and the Eastern Shore, the number of girls vaccinated through health departments rose from 289 before the mandate to about 950 the year after. Almost 1,500 were vaccinated last fiscal year.”<sup>48</sup> The mandate clearly affects public access for some of those who desire the vaccine. Those who do not want it are under no real obligation to get it; the exemption is so broad that the law clearly operates as more of a suggestion than a mandate. As a point of comparison, coverage of measles, mumps, and rubella (MMR) in Virginia is at 86%,<sup>49</sup> and that vaccination falls under the slightly more restrictive religious exemption in the statute.<sup>50</sup>

Despite the fact that the mandate does not actually force parents to do anything, it is exceedingly unpopular. University of Pennsylvania Center of Bioethics Director Arthur Caplan notes that because of the expansive nature of the exemption, “It’s not like they’re dragging young girls in by the hair to have them vaccinated.”<sup>51</sup> Regardless, in four out of the last five legisla-

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

<sup>45</sup> *Id.*

<sup>46</sup> Centers for Disease Control and Prevention, *National and State Vaccination Coverage Among Adolescents Aged 13 Through 17 Years — United States*, 2010, 60 MORBIDITY AND MORTALITY WEEKLY REPORT 1117, 1121–22 (2011), available at <http://www.cdc.gov/mmwr/pdf/wk/mm6033.pdf> [hereinafter *National and State Vaccination Coverage*].

<sup>47</sup> Elizabeth Simpson, *Five Years after HPV Vaccine Law, State Remains Split*, VA. PILOT, Feb. 5, 2012, available at <http://hamptonroads.com/2012/02/five-years-after-hpv-vaccine-law-state-remains-split>.

<sup>48</sup> *Id.*

<sup>49</sup> *National and State Vaccination Coverage*, *supra* note 47, at 1122.

<sup>50</sup> VA. CODE ANN. § 32.1-46 (2011) (“The provisions of this section shall not apply if: 1. The parent or guardian of the child objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices, unless an emergency or epidemic of disease has been declared by the Board . . . .”)

<sup>51</sup> Simpson, *supra* note 48.

tive sessions, the HPV vaccine requirement has faced repeal.<sup>52</sup>

## II. HOW IS THIS VACCINE DIFFERENT?

Gardasil is certainly not the only vaccine to engender controversy; parent groups have been resistant to other compulsory vaccination laws and programs.<sup>53</sup> However, there are meaningful differences between this vaccine and others, in terms of both the way public health theory and law treat vaccines, and how Americans have accepted the vaccine.

### A. Vaccination Within a Framework of Health Policy Theory and Law

#### 1. Vaccine Theory

##### i. Community Immunity

The first essential aspect of traditional vaccination theory is the medical concept of community, or “herd” immunity.<sup>54</sup> This theory addresses the certainty that public health professionals will never be able to vaccinate 100% of a population against a particular disease.<sup>55</sup> This is true both for medical reasons (infants, pregnant women, the elderly, and those with compromised immune systems like HIV patients or people undergoing chemotherapy are ineligible for many vaccinations) and for logistical realities; there are some people who will always evade regulation.<sup>56</sup> However, the principle of herd immunity suggests that once a population attains a critical

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<sup>52</sup> *HPV Vaccine*, NCSL.ORG, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified Apr. 2012).

<sup>53</sup> See GOSTIN, *supra* note 1, at 377 (noting that in early U.S. culture “opposition arose in many quarters. Some opponents expressed scientific objections about efficacy; some worried that vaccination transmitted disease or caused harmful effects; still others objected on grounds of religion or principle.”). This suspicion continues today. In 1998, a single medical study proposed a causal link between Thimerosal, a mercury preservative in some vaccines commonly administered to children—like the measles, mumps and rubella (“MMR”) vaccine—and autism. Thomas H. Maugh II, *Wakefield's Paper Linking MMR Vaccine and Autism a Fraud on the Scale of Pittdown Man*, *BMJ Editorial Says*, L. A. TIMES, Jan. 5, 2011, available at <http://articles.latimes.com/2011/jan/05/news/la-heb-andrew-wakefield-01052011>. The scientific community has since wholly rejected the study and its creator. *Id.* The Editor in Chief of *The British Medical Journal* has gone so far as to allege that it “was based not on bad science but on a deliberate fraud,” and after an extensive hearing on the matter the British General Medical Council revoked author Andrew Wakefield’s medical license in 2010. *Id.* However, as late as 2008 states in the U.S. were still legislating protections against the use of vaccinations containing Thimerosal at the behest of parent advocacy groups. GOSTIN, *supra* note 1, at 377. Clearly, suspicion of vaccinations runs very deep. These fears are grounded in a mistrust of the medical profession or conflicts with religious faith, and are bolstered by an American culture that stresses individual freedom, as well as the heightened anxiety all parents experience for the health of their children.

<sup>54</sup> *Community Immunity (“Herd” Immunity)*, NAT’L INST. OF ALLERGY AND INFECTIOUS DISEASES, (Oct. 21, 2010), <http://www.niaid.nih.gov/topics/pages/communityimmunity.aspx>

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

mass of immunized people, the individuals who remain unvaccinated will still be safe because the disease can no longer survive long enough to find still-vulnerable hosts.<sup>57</sup>

Opponents of standard vaccinations claim that the decision to not vaccinate their children or themselves is personal; that those who do not want a vaccine risk only their own health and the health of those who have made the same choice. However, when people choose to remain unvaccinated, they contribute to the overall unvaccinated proportion of a population, undermining herd immunity and exposing those who cannot be vaccinated to the disease.<sup>58</sup> For example, an unvaccinated seven-year-old child who contracts measles will likely have ample opportunity to spread the disease to children under 12 months of age (who are too young for the vaccine)<sup>59</sup> before the onset of symptoms alerts adults that the child should be quarantined.<sup>60</sup> Furthermore, “[n]o shot confers 100 percent immunity,” so those

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

<sup>58</sup> Sandra G. Boodman, *More Parents Refuse to Have Their Children Immunized*, MIAMI HERALD, June 17, 2008, available at <http://www.miamiherald.com/living/health/story/571720.html>; see also, Anne McGraw Reeves, *Commentary: Parents Refuse to Vaccinate Kids Over Questionable Claims*, PENNLIVE.COM, (Jan. 8, 2012), [http://www.pennlive.com/midstate/index.ssf/2012/01/commentary\\_protect\\_herd\\_immuni.html](http://www.pennlive.com/midstate/index.ssf/2012/01/commentary_protect_herd_immuni.html).

<sup>59</sup> *Vaccines and Preventable Diseases: Measles - Recommendations for Prevention*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/measles/dis-detail-rec.htm> (last modified Mar. 24, 2011).

<sup>60</sup> For an anecdotal portrayal of the effect this “personal choice” can have on people who have made no such choice, see *This American Life Broadcast 370: Ruining It for the Rest of Us*, NAT’L PUB. RADIO (Dec. 18, 2008), <http://www.thisamericanlife.org/radio-archives/episode/370/transcript>.

(Susan Burton: Here’s how one year old Finlee ended up in the quarantine. Hilary took her to daycare on a Monday morning. And one of the teachers asked, very sweetly, if Finlee had been vaccinated for measles yet. When Hilary said no, she was sent to the daycare office with Finlee in her arms. The room was packed with people. There was all kinds of commotion. And a woman from the Health Department standing there with a clipboard.

Hilary Chambers:

I walked up to her and was like, “what’s going on?” And she said, “you guys can’t be here right now.” And I said, “OK, if I take her to the doctor and get her shot today, can I bring her back tomorrow?” And she said, “She is not to leave your property for the next three weeks.” And my first reaction—I laughed out loud. And I asked her if she could babysit, because it was either that or freak out, which is what I did next. I mean it was so sudden. And I was scared. And also, what was I going to do for the next three weeks? My husband and I both work. And there were people everywhere, and my daughter, and I have to be at work in an hour.)

Another story from the same broadcast details the experience of a parent whose ten-month-old baby actually contracted measles during the same outbreak:

Susan Burton: Megan took her son to the emergency room. When she told them he might have measles, it took two hours for them to figure out how to get him inside the hospital without exposing everyone else. Finally, they came out with a blanket, wrapped him up, and rushed him into a secure room. He dropped from 18 pounds to 12 pounds in five days. The first thing they had to do was put in an IV. He was so dehydrated that his veins had collapsed. It took an hour and four nurses to get a needle into his wrist. Her



who ‘choose’ to remain unvaccinated may also undermine the choice made by those who prefer vaccination.<sup>61</sup>

Some members of the anti-vaccination community do appreciate the real possibility that their actions may harm other people, including children.<sup>62</sup> However, they consider danger to their own children more important than danger to other people’s children.<sup>63</sup> This is especially true of diseases that parents perceive as a lesser threat to their children—like measles, which most parents of small children have never seen because of fully established (until recently) herd immunity, or HPV, which parents believe children can avoid by maintaining a particular standard of behavior. Lawrence Gostin compares the resulting outbreaks of disease to the tragedy of the commons, and observes, “[f]rom a societal perspective, the choice not to immunize may be optimal to the individual if there is herd immunity; but in the aggregate, this choice could lead to the failure of that herd immunity.”<sup>64</sup>

## ii. A Theoretical Construct for Disease: Three Models

Next, it is instructive to consider the policy theory underlying different stakeholders’ perceptions of disease. One of the most complex elements of the Gardasil conflict is the different ways in which participants view both HPV and the vaccination against it. Lawrence Gostin theorizes that the confluence of immunization possibilities, the ability to screen for infections like tuberculosis, syphilis, and gonorrhea, and miracle treatments like antibiotics created the ideal conditions for development of comprehen-

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son was screaming. Megan couldn’t take it. She had to leave the room.

Megan Campbell: There were moments when I was worried that he wouldn’t make it because this fever just wasn’t letting up. This 106 fever and this rash that made my son look like an alien almost. And I almost wondered if he was going to look-- if he was going to be the same boy that he was a week before . . .

Susan Burton: Megan’s son was sick for weeks. Megan and her husband both had to take a month off work. They were dumping him into ice baths when his fever spiked, constantly watching for side effects of the measles, blindness, brain swelling. When it was all over, Megan and her husband found they couldn’t engage in the vaccine debate.

Megan Campbell: And I have very close friends who don’t vaccinate their children. And it’s just something that we can’t talk about. We get too angry. We can barely speak. *Id.*

<sup>61</sup> Sandra G. Boodman, Faith Lets Some Kids Skip Shots, WASH. POST, June 10, 2008, at HE01.

<sup>62</sup> See *This American Life Broadcast*, *supra* note 61.

<sup>63</sup> GOSTIN, *supra* note 1, at 378 (“The state is explicitly asking parents to forego their right to decide the welfare of their children, not necessarily for the child’s benefit but for the wider public good.”).

<sup>64</sup> GOSTIN, *supra* note 1, at 379; see also Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968).

sive public health policy at the beginning of the twentieth century.<sup>65</sup> However, he notes, just as fundamental to this development is a shared societal or political theory of how disease functions.<sup>66</sup> Gostin, Burris, and Lazzarini propose three distinct models for conceptualizing the function of disease: the microbial model, the behavioral model, and the ecological model.<sup>67</sup>

The microbial model is the most prominent and easily understood model.<sup>68</sup> It focuses solely on the microbial infections: their isolation, treatment, and prevention.<sup>69</sup> In many ways, this is the least controversial model<sup>70</sup> and is purportedly the model on which most jurisdictions base their immunization laws.<sup>71</sup> When public health officials talk about Gardasil, they speak only in terms of the microbial model—conceptualizing the problem as HPV and cancer, and the vaccine as the appropriate solution.<sup>72</sup>

Conversely, the behavioral model considers choice and individual responsibility, and places the human host at the foreground of the inquiry.<sup>73</sup> Under this model, the subject of public policy efforts is the personal conduct responsible for the contraction or development of the disease.<sup>74</sup> This could apply to a wide range of behaviors and diseases, from high calorie intake and heart disease, to needle sharing and HIV. In those examples, prevention efforts might entail programs to heighten public awareness of diet and nutrition, and school programs to discourage the drug use, respectively.

However, because this approach focuses on the cause and effect of human choices, and not the seemingly arbitrary interference of microorganisms, it opens up a space for conflict over the question of choice and morality.<sup>75</sup> Essentially, “[h]ealth can be seen not as a social good to be

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<sup>65</sup> GOSTIN, *supra* note 1, at 372–74.

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

<sup>67</sup> Lawrence O. Gostin et. al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 69–70 (1999).

<sup>68</sup> *Id.* at 70.

<sup>69</sup> *Id.* at 69–70.

<sup>70</sup> However, a restricted focus on pathogens may render the needs, rights, and concerns of people who serve as their victims ancillary to the discussion. *Id.* at 70. For example, HIV patients in the 1990s expressed great reluctance to comply with government efforts to track and monitor the spread of the disease through individual patients. *Id.* Though policymakers using the microbial model would consider such a measure to be an efficient means of studying the disease, patients might fear it as a harbinger of government surveillance of their lives, and judgment of their choices. Scott Burris, *Public Health, "AIDS Exceptionalism" and the Law*, 27 J. MARSHALL L. REV. 251, 251–54 (1994).

<sup>71</sup> Gostin et. al., *supra* note 68, at 70.

<sup>72</sup> Harris, *supra* note 37 (“This is cancer, for Pete’s sake,” said Dr. William Schaffner, chairman of the Department of Preventive Medicine at Vanderbilt University School of Medicine and a nonvoting member of the committee. “A vaccine against cancer was the dream of our youth.”).

<sup>73</sup> Gostin et. al., *supra* note 68, at 71.

<sup>74</sup> *Id.* at 72.

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

achieved by concerted social action, but as an individual's reward for virtuous living. Conversely, ill health can be viewed, at least in part, as a just desert for wrongful behavior."<sup>76</sup> Accordingly, Lawrence Lessig observes, policymakers may struggle when tinkering with disease-causing behaviors to remove the potential for disease but allow the actor to continue a behavior fraught with moral consequences.<sup>77</sup>

Primary examples of this are programs to distribute clean needles to intravenous drug users, and programs to distribute and encourage condom use. The latter is particularly instructive. Efforts to combat the spread of HIV in the 1990s included an intensive rebranding campaign to promote condom usage.<sup>78</sup> Programs managed to shift perceptions of condoms away from a statement impugning a sex partner's cleanliness, toward the notion that condoms were a responsible, respectable tool for all people engaging in sexual acts outside of a committed relationship.<sup>79</sup> However, this kind of value-shift may subvert the policy goals of other community stakeholders who feel that "shame at the sight of a condom or guilt about drug use usefully reinforces the belief that the behavior is wrong."<sup>80</sup> In its best light, such intransigence in the face of empirically proven disease prevention reflects a concern about the long-term effects of a disease-risking activity, and the lack of focus on the human element.

Third, policy-makers may consider the ecological model, which looks to the environments that produce heightened risk and exposure to diseases.<sup>81</sup> It "conceives of illness not as an external threat such as a pathogen or toxin, nor as a function of personal choices, but rather as a product of society's interaction with its environment."<sup>82</sup> This model does not discount the impact of microbial and behavioral causes for disease, but it considers them secondary elements in an inquiry that should be focused on larger, more abstract concerns like "social institutions and activities, human inequality, and economic activities."<sup>83</sup>

These models, taken in concert, provide a view of the conflicting constructs for disease that policymakers and their constituents must reconcile to create jurisdiction-wide standards, rules, and programs. Virginia's Gardasil requirement pits those in the medical profession who wish to treat HPV as a

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<sup>76</sup> *Id.*

<sup>77</sup> Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943, 1003 (1995).

<sup>78</sup> *Id.* at 1119–23.

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

<sup>80</sup> Gostin et. al., *supra* note 68, at 73.

<sup>81</sup> *Id.* at 74.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

microbial disease against those in the socially conservative community who see the problem through the behavioral model, and offers nothing to those who might see the problem through the third model.

## 2. Legislation and Judicial Challenges

### i. Vaccination Legislation

The first compulsory immunization law appeared in Massachusetts in 1809, and the first immunization requirement for school attendance came eighteen years later in the same state.<sup>84</sup> In 1905, the year the Supreme Court handed down its seminal ruling on compulsory vaccines in *Jacobson v. Massachusetts*, almost half of the states required children entering public school to get certain immunizations.<sup>85</sup> Most states that did not previously have mandatory immunization statutes for school children passed them after measles outbreaks in the 1960s and 1970s.<sup>86</sup> At that time, it was evident that there was a 50% difference in outbreaks between states with strictly enforced school immunization requirements and states without.<sup>87</sup>

Today, all fifty states have some form of immunization requirement for public school attendance, and a corresponding “opt-out” provision for parents in certain circumstances.<sup>88</sup> All states recognize the right of parents to exempt their children from a vaccination requirement “when it can be reasonably predicted that a child would experience adverse effects from a vaccination.”<sup>89</sup> All states but Arizona, Mississippi, Missouri and West Virginia provide a religiously based opt-out,<sup>90</sup> and eighteen states provide a more

<sup>84</sup> GOSTIN, *supra* note 1, at 180–81. See also Charles L. Jackson, *State Laws on Compulsory Immunization in the United States*, 84 PUB. HEALTH REP. 787 (1969).

<sup>85</sup> GOSTIN, *supra* note 1, at 181.

<sup>86</sup> *Id.*

<sup>87</sup> Centers for Disease Control and Prevention, *Measles and School Immunization Requirements—United States*, MORBIDITY AND MORTALITY WEEKLY REPORTS (1978).

<sup>88</sup> Alexandra M. Stewart & Marisa Cox, *HPV Vaccine School Entry Requirements: Confronting the Myths, Misperceptions and Misgivings*, 4 J. HEALTH & BIOMED. L. 311, 321 (2008).

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

<sup>90</sup> *Id.*; see, e.g., Position Statement, The Pediatric Infectious Disease Society, A Statement Regarding Personal Belief Exemption from Immunization Mandates (Mar. 2011), available at <http://www.pids.org/images/stories/pdf/pids-pbe-statement.pdf>.

The Pediatric Infectious Diseases Society is the world’s largest organization of individuals dedicated to the treatment, control, and eradication of infectious diseases in children. As such, and given the background and rationale outlined below, the society opposes any legislation or regulation that would allow children to be exempted from mandatory immunizations based simply on their parents’, or, in the case of adolescents, their own, secular personal beliefs. It is recognized that in some states, failure to pass personal belief exemption legislation or regulation could result in public backlash that will erode support for immunization mandates. If legislation or regulation is being considered in this situation, it should contain the following provisions, which are intended to minimize use of

secular opt-put for parents who oppose vaccinations for philosophical reasons.<sup>91</sup>

## ii. Judicial Challenges

Theorists propose many layers of analysis in which policymakers must engage before coming to the conclusion that they may force immunization upon their constituents, including the vaccine's potential risks, the best interests of incompetents like children, social values, least restrictive means by which to prevent disease, scientific uncertainty, and the allocation of burdens and costs.<sup>92</sup> However, from a strictly legal standpoint, the states derive their power to legislate immunization requirements from the Police Power afforded them under the Tenth Amendment, which provides them with "the inherent authority . . . to impose restrictions on private rights for the sake of public welfare, order, and security."<sup>93</sup>

Nearly a century after the first compulsory vaccination law, the Supreme Court finally weighed in on whether states could force citizens to undergo inoculations, in *Jacobson v. Massachusetts*.<sup>94</sup> The answer was a resounding affirmation of the state's ability to legislate intrusive mandates in the name of public welfare under the state Police Power: "[t]here are manifold re-

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exemptions as the "path of least resistance" for children who are behind on immunizations (whereby it would be easier to obtain an exemption than to catch-up the child's immunizations):

The personal belief against immunization must be sincere and firmly held.

— Before a child is granted an exemption, the parents or guardians must receive state-approved counseling that delineates the personal and public health importance of immunization, the scientific basis for safety of vaccines, and the consequences of exemption for their child as well as other children in the community who are vulnerable to disease and cannot otherwise be protected.

— Before a child is granted an exemption, the parents or guardians must sign a statement that delineates the basis, strength, and duration of their belief; their understanding of the risks that refusal to immunize has on their child's health and the health of others (including the potential for serious illness or death); and their acknowledgement that they are making the decision not to vaccinate on behalf of their child.

— Parents and guardians who claim exemptions should be required to revisit the decision annually with a state-approved counselor and should be required to sign a statement each year to renew the exemption.

— Children should be barred from school attendance and other group activities if there is an outbreak of a disease that is preventable by a vaccination from which they have been exempted. Parents and guardians who claim exemptions for their children should acknowledge in writing their understanding that this will occur.

— States that adopt provisions for personal belief exemptions should track exemption rates and periodically reassess the impact that exemptions may have on disease rates.

<sup>91</sup> Stewart & Cox, *supra* note 89, at 321.

<sup>92</sup> GOSTIN, *supra* note 1, at 46–74.

<sup>93</sup> Stewart & Cox, *supra* note 89, at 318.

<sup>94</sup> *Jacobson v. United States*, 197 U.S. 11, 11 (1905).

straints to which every person is necessarily subject for the common good.”<sup>95</sup> In pursuing this common good, “a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.”<sup>96</sup> Stressing the republican nature of state and local lawmaking,<sup>97</sup> the Court dismissed the question of whether compulsory vaccination impinged on a citizen’s right of personal liberty.<sup>98</sup> The Court declared that “the liberty secured by the Constitution . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.”<sup>99</sup> As a measure of order,<sup>100</sup> the Court reasoned, “[e]ven liberty itself, the greatest of all rights, is not unrestricted license to act according to one’s own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is, then, liberty regulated by law.”<sup>101</sup>

### iii. Enforcement

One of the greatest barriers to compulsory vaccine law enforcement is the number of exemption provisions many laws now contain. There is significant concern within the medical community that parents who have not vaccinated their children as a result of inconvenience or negligence will utilize religious or philosophical exemptions as a “path of least resistance.” Or, as one vaccine researcher at the Johns Hopkins Bloomberg School of Public Health put it, “filing for an exemption should at least be a function of conviction, not laziness.”<sup>102</sup> Current estimates show that roughly 74.9% of school-age children in the United States have received standard childhood vaccinations.<sup>103</sup> Virginia’s numbers have fluctuated in the past few years between 65 – 72%.<sup>104</sup> There have been a recent rash of outbreaks of diseases like measles, whooping cough, and tuberculosis in urban areas, and many in the public health field suspect falling vaccination rates.<sup>105</sup> However, it is important to contrast standard vaccination coverage issues (where the state

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<sup>95</sup> *Id.* at 26.

<sup>96</sup> *Id.* at 26–27.

<sup>97</sup> *Id.* at 35.

<sup>98</sup> *Id.* at 26.

<sup>99</sup> Jacobson, 197 U.S. at 26.

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

<sup>101</sup> *Id.* at 26–27.

<sup>102</sup> Boodman, *supra* note 62.

<sup>103</sup> *Immunization*, VIRGINIA.GOV, <http://vaperforms.virginia.gov/indicators/healthfamily/immunization.php> (last modified Nov. 15, 2011).

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

<sup>105</sup> Associated Press, *Indiana Measles Outbreak Illustrates Disease Risk*, IBI.COM, Feb. 15, 2012, <http://www.ibj.com/indiana-measles-outbreak-illustrates-disease-risk/PARAMS/article/32689>.

may fall short of the approximate 95% rate necessary to establish herd immunity by 5–15%), and HPV coverage (where even the state with the greatest success thus far is 55%).<sup>106</sup>

## B. The Difference between Traditional Vaccine Policy and Gardasil Policy

### 1. Mandate Misdirection: the HPV Vaccination and the Culture War

In most standard vaccination policy confrontations, there are two key groups: those who perceive the disease through the microbial model, and those who do not trust doctors enough to allow one to stick them with a needle full of chemicals.<sup>107</sup> As the above section demonstrates, the latter group can have an impact on the results of vaccine policy, and some states have changed their laws to accommodate concerns like a fear of mercury, or to create wider exemption provisions.<sup>108</sup> However, this group has not come close to convincing a state to abandon its compulsory vaccination altogether.

The Gardasil debate, however, includes a third group: social conservatives who perceive HPV through the behavioral model, and do not wish to merely inoculate children against the disease. It is crucially important to note that these groups largely do not dislike the HPV vaccine because it cures a sexually transmitted disease, or because it removes an impediment between teenagers and sex. Unfortunately however, this is the portrayal of opposition common in media reports,<sup>109</sup> and is fueled by anti-vaccine statements of socially conservative politician such as Michelle Bachmann during the Republican primary. Social conservatives oppose the mandate because it subverts parental choice.<sup>110</sup> A spokesman for the Christian Medical and Dental Associations explained, “Parents should have the choice. There are

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<sup>106</sup> See *Op-Ed: Treating Families That Don't Immunize*, NAT'L PUB. RADIO, Dec. 5, 2012, <http://www.npr.org/2011/12/05/143147462/op-ed-treating-families-that-dont-immunize>.

<sup>107</sup> See GOSTIN, *supra* note 1, at 377.

(Public discourse about vaccination is often tense, with scientists and laypersons frequently talking at cross-purposes. Scientists dispassionately measure the population benefits against economic costs, concluding that vaccines are among the most cost-effective strategies. The lay public, however, often mistrust expert claims, despite the safety and efficacy of vaccination).

<sup>108</sup> See *supra* notes 103–07, and accompanying text.

<sup>109</sup> See Gerson, *supra* note 7 (“Try to imagine a parent-daughter conversation about sexual restraint and maturity that includes the words: ‘Honey, I’m going to deny you a vaccine that prevents a horrible, bleeding cancer, just as a little reminder of the religious values I’ve been trying to teach you.’ This would be morally monstrous. Such ethical electroshock therapy has nothing to do with cultivation of character in children. It certainly has nothing to do with Christianity, which teaches that moral rules are created for the benefit of the individual, not to punish them with preventable death.”).

<sup>110</sup> Rob Stein, *Cervical Cancer Vaccine Gets Injected With a Social Issue*, WASH. POST, Oct. 31, 2005, <http://www.washingtonpost.com/wp-dyn/content/article/2005/10/30/AR2005103000747.html>.

those who would say, ‘We can provide a better, healthier alternative than the vaccine, and that is to teach abstinence.’”<sup>111</sup> In fact, many social conservatives perceive the vaccine as force for good. Focus on the Family’s position statement praises the vaccine, and calls for its “universal availability”:

Recognizing the worldwide detriment to individuals and families resulting from HPV, Focus on the Family supports and encourages the development of safe, effective and ethical vaccines against HPV, as well as other viruses. The use of these vaccines may prevent many cases of cervical cancer, thus potentially saving the lives of hundreds of thousands of women across the globe.<sup>112</sup>

The Family Research Council also urges parents to consider vaccinating their children at the recommended age, as it “could provide a unique opportunity to reinforce a risk avoidance or abstinence message as the best form of prevention against HPV infection, as well as the many other negative outcomes associated with adolescent sexual activity.”<sup>113</sup> Both organizations recognize that factors other than individual choice—like rape, spousal infidelity, or past spousal indiscretions—may cause a person to contract HPV.<sup>114</sup> Both organizations recommend to members that the Gardasil vaccine is safe.<sup>115</sup> John Brehany, Executive Director of the Catholic Medical Association, counsels followers that “[h]ealing and preventing diseases, no matter what their source, are acts of mercy and a moral good.”<sup>116</sup> These publications make it clear that this position does not reflect a lack of knowledge about herd immunity, vaccine policy, or the ways in which HPV can be seen through the microbial model.

With respect to the place of vaccines in society, including the HPV vaccine, these groups do not necessarily reject science, compassion, or common sense. Focus on the Family is wholly supportive of standard childhood vaccinations, which they perceive through the microbial model, abstaining from any mention of the virtue of exemption provisions, even religious ones (FRC has no position on standard vaccinations).<sup>117</sup> Rather, they oppose

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<sup>111</sup> *Id.*

<sup>112</sup> Position Statement, Focus on the Family, HPV Vaccine, *available at* [http://www.focusonthefamily.com/topicinfo/Position\\_Statement-Human\\_Papillomavirus\\_Vaccine.pdf](http://www.focusonthefamily.com/topicinfo/Position_Statement-Human_Papillomavirus_Vaccine.pdf).

<sup>113</sup> Moira Gaul, *Gardasil: What Every Parent Should Know About the New Vaccine*, FAMILY RESEARCH COUNCIL 5–6 (2007), <http://downloads.frc.org/EF/EF07H25.pdf> [hereinafter *Gardasil*].

<sup>114</sup> *Id.*; *see also*, Position Statement: HPV Vaccine, *supra*, note 113.

<sup>115</sup> *See Gardasil, supra*, note 114.

<sup>116</sup> *CMA Issues Statement on Implementation of HPV Vaccine*, CATHOLIC MED. ASSOC., June 24, 2009, [http://www.cathmed.org/issues\\_resources/publications/press\\_releases/cma\\_issues\\_statement\\_on\\_implementation\\_of\\_hpv\\_vaccine/](http://www.cathmed.org/issues_resources/publications/press_releases/cma_issues_statement_on_implementation_of_hpv_vaccine/).

<sup>117</sup> For a full-throated defense of standard childhood vaccinations and the medical professionals that provide them, see Position Statement, Focus on the Family, Vaccine Safety (Nov. 2010), *available at* [http://www.focusonthefamily.com/topicinfo/Vaccine\\_Safety.pdf](http://www.focusonthefamily.com/topicinfo/Vaccine_Safety.pdf).

I know people who have never been immunized and yet have never contracted these dis-



HPV vaccine mandates because of the potential for coercion, and because they further a solution to a sexually transmitted disease that is germ-centered instead of human-centered.<sup>118</sup> Social conservatives who object to the mandate feel that a needle in the arm is an insufficient uniform policy for a disease with a behavioral component. A spokesman for the Christian Medical and Dental Associations explained, “parents should have the choice. There are those who would say, ‘we can provide a better, healthier alternative than the vaccine, and that is to teach abstinence.’”<sup>119</sup> This is not always the position reflected in the news media. Upon Gardasil’s release, an analyst at Focus on the Family observed, “[w]e support this vaccine. We see it as an extremely important medical breakthrough. To read those headlines saying we’re against this is really disconcerting.”<sup>120</sup>

Dr. Karen Loeb Lifford, medical director for Planned Parenthood in Massachusetts, notes that opposition to the mandate on these grounds “sounds incredibly reasonable. Who can disagree with parents making health decisions for their children? But take a closer look at that argument: it’s denying the vaccine to many people who won’t have access to it unless it’s mandatory.”<sup>121</sup> Lifford catalogues the ways in which the mandate affects access:

Many parents might not know to ask for it, or be able to afford it. “If it’s available in theory but it costs \$375, it’s not available to everybody. If it’s only effective before women have been exposed to HPV, we’ve missed our opportunity.” Besides, she says, every state already has a law allowing parents to decline vaccination on religious grounds without their kids being banned from school.

cases. Doesn’t this support the idea that children don’t need to be vaccinated?

It’s true that people who are not immunized may never become infected with diseases such as mumps or measles. These people are most likely the beneficiaries of herd immunity, a phenomenon that relies on a buffer of immunized individuals between infected persons and unvaccinated ones. For example, someone with a disease that is spread from person to person may encounter many individuals during the course of his or her infection. If few people in the community are immunized against the disease, the chance of it being spread throughout the community is higher than it would be if many people are immunized. As more people are immunized, the chance of an unvaccinated individual coming in contact with the infected person (and thereby possibly contracting the disease) becomes smaller. Herd immunity requires that a large number of people in the community be immunized. In regions where vaccination rates drop, herd immunity decreases and the incidence of disease rises. Thus refusing vaccination not only puts individuals at risk but may also increase the risk of disease for others in the community.

<sup>118</sup> See Gardasil, *supra*, note 114.

<sup>119</sup> Stein, *supra* note 111.

<sup>120</sup> Nancy Gibbs, Defusing the War Over the “Promiscuity” Vaccine, *TIME*, June 21, 2006, <http://www.time.com/time/nation/article/0,8599,1206813,00.html>.

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

But “by making it mandatory, you make it accessible.”<sup>122</sup>

In practice, the assertion that requiring the vaccine is enough to successfully increase access has turned out to be dismally incorrect.

## 2. The Problem of Access

As mentioned above, national coverage rates for the vaccine have been very low—26.7% of girls and 1% of boys are fully vaccinated.<sup>123</sup> Since 2006, forty-one states have attempted to pass some kind of legislation to promote vaccination coverage, and nineteen have succeeded.<sup>124</sup> Virginia and Washington D.C. are the outliers with mandates, but many other states have passed laws and regulations to improve access to Gardasil, and information about its use.<sup>125</sup> States have attempted to accomplish this goal through a variety of policy initiatives, including requirements that schools offer the vaccine to students, requiring some or all types of insurance plans to cover the vaccine, and adding the vaccine to Medicaid coverage.<sup>126</sup> At the same time, however, they have also put in place roadblocks to accessibility, like failing to fund such programs,<sup>127</sup> prohibiting physicians from administering VFC<sup>128</sup> vaccines to children who have insurance that does not cover vaccinations, and failing to regulate insurance reimbursement practices to physicians.<sup>129</sup>

The latter has proven one of the most serious and ignored obstacles to HPV inoculation in the U.S., as pediatricians struggle to pay for the costs of

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<sup>122</sup> *Id.*

<sup>123</sup> See *supra*, notes 33–34, and accompanying text.

<sup>124</sup> HPV Vaccine, NCSL.ORG, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified June 2012).

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

<sup>126</sup> *Id.*

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

<sup>128</sup> Inequality of Immunization Coverage, TENN. MEDICAL MAGAZINE, May 26, 2010, <http://www.hamblenpeds.com/index.php/Articles/inequality-of-immunization-coverage.html>

(VFC is a federal program that furnishes vaccines for TennCare patients, those patients without insurance, American Indians, Eskimos’ and those that have insurance, but insurance does not cover the cost. Each state’s VFC program may select whether private offices can administer the VFC immunization to those without adequate wellness benefits. The State of Tennessee has chosen that rather than receiving the vaccines (immunization) in the physicians’ offices, the parent must make an additional trip to the health department in order to vaccinate their child. This puts a hardship on the working parent, a contributing tax payer, as they have already taken time off for their child to be seen at the pediatrician’s office. )

<sup>129</sup> Sandra G. Boodman, *Who Gets Stuck?*, WASH. POST, May 1, 2007, <http://www.washingtonpost.com/wp-dyn/content/article/2007/04/27/AR2007042702631.html>.

the vaccination.<sup>130</sup> Often insurance companies do not reimburse doctors for the full cost of the vaccine, or cover only the sticker price of the inoculation, but not the staff time required to order, administer, and conduct proper filing for it.<sup>131</sup> Many insurance companies also drag their feet when sending reimbursement funds, and checks do not arrive in time, forcing doctors to pay suppliers out of their own pockets.<sup>132</sup> Most other childhood vaccinations cost doctors roughly \$50 per dose, but one dose of Gardasil costs nearly three times that.<sup>133</sup> As a result, many pediatricians have stopped providing Gardasil to patients.<sup>134</sup> Thus, when surveyed, providers express more support for policy initiatives that regulate the payment side of HPV vaccination than for compulsory vaccination laws for school attendance.<sup>135</sup>

With these concerns in mind, it is imperative to examine five years of results. Because of the mandate, Virginia was able to distribute approximately 2,500 doses from state funds, thus access has improved.<sup>136</sup> When compared to other state results, however, this seems like a paltry increase. Nine states—Connecticut (45.5%), Massachusetts (46.8%), Nebraska (42.5%), New Hampshire (42.2%), Pennsylvania (41.7%), Rhode Island (55.1%), South Dakota (54.5%), Washington (45.5%), Wisconsin (44.1%)—and the City of New York (the CDC disaggregates for very populous urban areas) have surpassed Virginia.<sup>137</sup> Five of them have passed laws that promote accessibility.<sup>138</sup> The only two states to surpass 50%—Rhode Island and South Dakota—have two of the strongest accessibility laws. Rhode Island requires all insurance companies to cover the full cost of the “administration” of the vaccine.<sup>139</sup> South Dakota has pledged an unprecedented amount of state funds to support vaccination of girls aged 9–11: 9.2 million dollars.<sup>140</sup>

Accessibility initiatives can coexist with mandatory inoculation, but some public health experts believe they might work against each other.<sup>141</sup>

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<sup>130</sup> *Inequality of Immunization Coverage*, TENN. MED. MAG., May 26, 2010, <http://www.hamblenpeds.com/index.php/Articles/inequality-of-immunization-coverage.html>

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> Gudeman, *supra* note 31.

<sup>134</sup> Boodman, *supra* note 130.

<sup>135</sup> *HPV Vaccination of Women*, *supra* note 29.

<sup>136</sup> *See supra* note 48, and accompanying text.

<sup>137</sup> *National and State Vaccination Coverage*, *supra* note 47.

<sup>138</sup> *Id.*; *HPV Vaccine*, NCSL.ORG, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified June 2012).

<sup>139</sup> *HPV Vaccine*, NCSL.ORG, <http://www.ncsl.org/issues-research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last modified June 2012).

<sup>140</sup> *Id.*

<sup>141</sup> Pam Belluck, *In New Hampshire, Soft Sell Eases Vaccine Fears*, N.Y. TIMES, May 12, 2007, available at <http://www.nytimes.com/2007/05/12/health/12cancer.html>.

New Hampshire is one example.<sup>142</sup> After Gardasil's approval by the FDA, the Health and Human Services (HHS) Department announced that it would provide the vaccine at no charge to girls under the age of 18.<sup>143</sup> The response was a tidal wave of demand, with virtually no parental blowback.<sup>144</sup> Health care providers that offered the vaccine developed long waiting lists.<sup>145</sup> News coverage of initiative glowed with admiration, describing the state as a place "where people wear their independent streaks with pride." HHS spokesman Greg Moore opined, "I suspect that we're not seeing a significant controversy because there was a never a discussion about whether to make this mandatory."<sup>146</sup>

New Hampshire's coverage rate is only 42.2%, which is less than a full percentage point above Virginia's, at 41.5%.<sup>147</sup> However, the larger picture demonstrates that mandates are not the definitive means by which to increase access. The District of Columbia, the other jurisdiction with a mandate, is at 33.8%, and there are ten more states and two counties (El Paso, Texas and Philadelphia, Pennsylvania) that exceed that number.<sup>148</sup> Here again, mandates do not effect meaningful access: "Christina Sprague of Northwest Washington said she has spent several hours on the phone in recent months trying to find a doctor who will immunize her daughter, who attends an out-of-state college. 'It's been pretty frustrating,' Sprague said. 'This should be straightforward.'"<sup>149</sup> Nationwide, access to the HPV vaccine is much more difficult than gaining access to standard vaccinations. While mandating the vaccination does cause higher coverage, it is clearly not the only (or most successful) means by which to do so.

### III. PUBLIC POLICY SOLUTIONS

#### A. Option 1: Fight for More, Better Mandates Nationwide

From the medical and public health side of the divide, there can be no compromise. There is a disease without a cure, but a vaccine to prevent it, and any approach other than forcible compliance will not work. This section will consider whether states can legally institute HPV vaccine man-

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<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> Pam Belluck, *In New Hampshire, Soft Sell Eases Vaccine Fears*, N.Y. TIMES, May 12, 2007, <http://www.nytimes.com/2007/05/12/health/12cancer.html>.

<sup>147</sup> *National and State Vaccination Coverage*, *supra*, note 47.

<sup>148</sup> *Id.*

<sup>149</sup> Boodman, *supra* note 130.

dates that provide an exemption solely for those children who cannot medically receive the inoculation.

### 1. Public Health Justifications

From a public health law perspective, mandating the HPV vaccination is easily legitimate. Legally, it is an established principle that mandatory vaccines are within the purview of the state under its police power.<sup>150</sup> Under *Jacobson*, if a state legislature passes a law requiring a population to undergo vaccination, that law is valid, regardless of the religious or moral convictions of the individual recipient.<sup>151</sup>

From a policy standpoint, the vaccine is advisable because it is a safe and effective means of preventing disease.<sup>152</sup> It is also relatively easy to dispense with the socially conservative fear that the vaccine will incentivize risky and unhealthy sexual choices—an effect known as “behavioral disinhibition.”<sup>153</sup> No research on this specific question exists currently, but it is instructive to draw conclusions about research collected on needle exchange and condom distribution participants. Consistently, behavioral disinhibition studies demonstrate that:

1) Injection drug users did not increase drug use when they were offered free needle exchanges to reduce HIV infection; 2) Adolescents did not change reported rates of sexual activity or increase the frequency of unprotected intercourse when adolescents were made aware of the availability of emergency contraception; and 3) The percentage of adolescents who had ever had sex did not change after having condoms available, or between schools that have instituted Condom Availability Programs (CAP)s and those without such programs.<sup>154</sup>

Indiana Health Commissioner Dr. Judy Monroe has states it more bluntly, “[t]here's no evidence that seat belts have increased reckless driving. There is no evidence that when we get tetanus shots, we seek rusty nails.”<sup>155</sup> Thus, from a public health standpoint, legally and practically, a strict mandate with a tight exemption provision would be an advisably policy goal.

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<sup>150</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905).

<sup>151</sup> *Id.* at 29–30.

<sup>152</sup> See *supra* notes 36–42, and accompanying text.

<sup>153</sup> Stewart & Cox, *supra* note 89, at 328.

<sup>154</sup> *Id.* at 328–29.

<sup>155</sup> *Id.* at 329.

## 1. Reproductive Rights Justifications

One potential wrinkle in that analysis is that *Jacobson* was decided in an era that could not foresee the development of the substantive due process doctrine and the Court's decisions in *Griswold v. Connecticut* and *Roe v. Wade*.<sup>156</sup> Gardasil is more polarizing than other vaccines, and much of the resistance comes from its association with sexual decision-making. Those who oppose the vaccine, especially under a state regime of mandatory vaccination, do so because they believe they have the individual right to choose the standard of sexual morality that makes it medically necessary, and to choose whether or not to violate their bodily integrity with a needle and the quadrivalent vaccination it contains.<sup>157</sup> Both of these choices implicate reproductive jurisprudence, and this sub-section will attempt to unpack those elements of the conflict.

In *Lawrence v. Texas*, Justice Kennedy begins his opinion by extolling the virtues of liberty within the substantive due process doctrine. "Liberty presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct. The instant case involves liberty of the person both in its spatial and in its more transcendent dimensions."<sup>158</sup> This line of cases, going back to *Griswold*, honors the right of privacy, and of certain decisional autonomy within that sphere.<sup>159</sup> The *Griswold* Court focused more on describing the parameters of penumbras<sup>160</sup> and paying homage to the ancient legitimacy of marital privacy.<sup>161</sup> However the Court more explicitly addresses individual privacy in *Eisenstadt*, certifying "the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."<sup>162</sup> More instructive in the Gardasil debate, however, are the *Roe* and *Casey* decisions, which consider the liberty interest of people who are not alone in their choices. When a parent decides that a child should not receive the Gardasil vaccine, that decision affects the lives of other people besides the decision-maker.

In *Roe*, the Court ruled that the state cannot proscribe all abortions; that the pregnant woman retains the right during the first trimester of her preg-

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<sup>156</sup> *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Roe v. Wade*, 410 U.S. 113 (1973).

<sup>157</sup> See *supra* notes 118–21, and accompanying text.

<sup>158</sup> *Lawrence v. Texas*, 539 U.S. 558, 562 (2003).

<sup>159</sup> *Griswold*, 381 U.S. at 479.

<sup>160</sup> *Id.* at 482–86.

<sup>161</sup> *Id.* at 486.

<sup>162</sup> *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (emphasis in original).

nancy to seek out an abortion without state interference.<sup>163</sup> *Casey* modified that standard, giving women until viability to make their choice, but permitting states regulate it, so long as those regulations do not unduly burden, or have the “purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion.”<sup>164</sup> In both cases, the Court confirmed that the state has a powerful interest in the life of a pregnant woman’s unborn child.<sup>165</sup> However, it concluded that the “urgent claims of the woman to retain the ultimate control over her destiny and her body, claims implicit in the meaning of liberty,” permitting the woman to retain a limited right to end fetal life.<sup>166</sup> It affirmed precedents that “respected the private realm of family life which the state cannot enter.”<sup>167</sup> Truly, *Casey* paints an evocative picture of what privacy means: “[t]hese matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.”<sup>168</sup> Accordingly, the Court explains, “at the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.<sup>169</sup> Furthermore, it explicitly recognized that “*Roe*... may be seen not only as an exemplar of *Griswold* liberty but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection.<sup>170</sup>

This language would seem to have curious implications within the Gardasil debate. As anti-vaccine groups proliferate with slogans like “Your Health. Your Family. Your Choice.”<sup>171</sup> does it follow that they have a legal basis to oppose mandatory vaccination in abortion rights case law? Furthermore, is it inconsistent for reproductive rights organizations to claim that women should have autonomy over their own bodies with respect to abortion and contraception, but that women and girls should be forced to surrender that autonomy and bodily integrity with respect to mandatory HPV vaccination? Of course, that inconsistency applies to the other side of

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<sup>163</sup> *Roe v. Wade*, 410 U.S. 113, 164 (1973), holding modified by *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992).

<sup>164</sup> *Planned Parenthood*, 505 U.S. at 877.

<sup>165</sup> *Roe*, 410 U.S. at 163; *Planned Parenthood*, 505 U.S. at 860.

<sup>166</sup> *Planned Parenthood*, 505 U.S. at 869.

<sup>167</sup> *Id.* at 851 (quoting *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944)).

<sup>168</sup> *Planned Parenthood*, 505 U.S. at 851.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 857.

<sup>171</sup> NAT’L VACCINE INFO. CTR., <http://www.nvic.org/> (last visited May 1, 2012).

the debate. Many of the same groups that wholly oppose abortion rights,<sup>172</sup> like Focus on the Family and the Family Research Council, also oppose making Gardasil mandatory.<sup>173</sup> Regardless, requiring vaccination even of those who do not want it could be construed as an intrusive violation of their bodily integrity. And because HPV is transmitted by sex, it could also constitute state intervention in their right to make private, individual decisions about sex and its consequences.

However, this argument ignores the reality that the *Casey* court imposed wide limits on the right to make the abortion choice, stemming mostly from the state's concern for the life of the unborn, who have no choice in the abortion decision. At the point of viability, or "the independent existence of the second life," states may "override . . . the rights of the woman."<sup>174</sup> Citing *Jacobson*, the *Roe* Court insisted that

a State may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life. . . . The privacy right involved, therefore, cannot be said to be absolute. In fact, it is not clear to us that the claim asserted by some amici that one has an unlimited right to do with one's body as one pleases bears a close relationship to the right of privacy previously articulated in the Court's decisions. The Court has refused to recognize an unlimited right of this kind in the past.<sup>175</sup>

Additionally, both *Roe* and *Casey* consider as part of the abortion inquiry the role of women's suffering as a result of pregnancy, childbirth, and motherhood. *Roe* lists the many difficulties that women have to endure,<sup>176</sup> and *Casey* considers, "that the inability to provide for the nurture and care of the infant is a cruelty to the child and an anguish to the parent,"<sup>177</sup> and that "[t]he mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear."<sup>178</sup> The Court clearly

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<sup>172</sup> See *Our Position (Abortion)*, FOCUS ON THE FAMILY, <http://www.focusonthefamily.com/socialissues/social-issues/abortion/our-position.aspx> (last visited May 1, 2012); *Human Life & Bioethics*, FAMILY RESEARCH COUNCIL, <http://www.frc.org/life--bioethics> (last visited May 1, 2012).

<sup>173</sup> See *supra* note 120, and accompanying text.

<sup>174</sup> *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 870 (1992).

<sup>175</sup> *Roe v. Wade*, 410 U.S. 113, 154 (1973).

<sup>176</sup> *Id.* at 153.

(Specific and direct harm medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it. In other cases, as in this one, the additional difficulties and continuing stigma of unwed motherhood may be involved. All these are factors the woman and her responsible physician necessarily will consider in consultation.)

<sup>177</sup> *Planned Parenthood*, 505 U.S. at 853.

<sup>178</sup> *Id.* at 852.



factors those concerns into its definition of the liberty interest, and its decision to allow some space for the woman to choose to end a pregnancy.<sup>179</sup> Applied to the Gardasil debate, this powerful rationale disappears. Getting a vaccination, for those who are medically able, entails few if no burdens, none of them close to the scale of the burdens of pregnancy and motherhood. Thus, the liberty interests involved are more abstract.

When parents refuse the HPV vaccine for their children, they force those children to choose between sexual autonomy and safety from a virus that causes cancer.<sup>180</sup> In the event that an unvaccinated child chooses to have sex (inside or outside the bonds of marriage), or is the victim of rape, she faces possible exposure to the virus. If exposed, that child then poses a threat to any other person with whom she wishes to partner sexually. Those who would reserve the right to force such circumstances on their children find no support in reproductive rights jurisprudence, which soundly refutes the right of the individual to harm an independent human life in service of her own liberty. Rather, because of the extreme potential harm to parties other than the decision-maker, reproductive rights law solidly supports the right of a state to compel girls to give over their arms and decision-making capacity in the context of a mandatory vaccination for HPV.

#### B. Option 2: The Pragmatic Alternative

In her student note, Christina Hud cheerfully asserts,

Given HPV's high prevalence and harmful effects, the Virginia General Assembly can supersede parental objections to vaccination when enforcing this law. As is evidenced by the research featured in this Note, courts have traditionally chosen to protect the public health over individual interests. If one compares the unsupported risks of supposed promiscuity at a young age with the benefit of potentially eradicating anogenital warts and drastically reducing cervical cancer later in life, it is evident that logic favors mandating vaccination.<sup>181</sup>

Hud advocates for the previous strategy, because she understands the problem as a microbial disease with a simple solution. Nevertheless, she, along with the public health community, fails to account for the powerful opposition against HPV vaccination mandates that exist in U.S. society. The Virginia General Assembly could pass that law, but it will not do so, at least for the foreseeable future; and despite many attempts, neither will any

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<sup>179</sup> *Id.*

<sup>180</sup> *See Bellotti v. Baird*, 443 U.S. 622, 633 (1979) ("A child, merely on account of his minority, is not beyond the protection of the Constitution.").

<sup>181</sup> Hud, *supra* note 41, at 265.

other state. Currently, the reality of the HPV vaccination debate is that the public health community, which sees HPV through the microbial model, and the socially conservative community, which sees HPV through the behavioral model, cannot come to a consensus on the right way to fight the disease. Meanwhile, the high cost of the vaccine and lack of knowledge about its safety and efficacy are proving a much more serious obstacle in the way of greater coverage.

Though Virginia's mandate has clearly elevated its coverage levels, a comparison of coverage rates nationwide demonstrates that accessibility laws tend to have a much stronger impact. Mandates and accessibility laws are not mutually exclusive options, and ideally Virginia would be able to institute both without controversy or debate, but sometimes a closed system of political capital requires that people make compromises. If Virginia cannot have both an effective mandate and improved access to the vaccine, it should pursue the more effective option. In the next legislative session, public health advocates should consider a legislative coalition with social conservative groups to broker a deal to repeal the Gardasil mandate. In exchange, they should lobby for much more extensive funding for vaccine administration and education, as well as insurance reform that requires health insurance companies to cover the full cost of administering the vaccine, and to pay doctors in a timely manner. Legislators could also attempt to manage the consequences of the HPV crisis from the back end, procuring funds for Pap smears and education. This coalition need not be limited to lobbying efforts, however. Without a mandate that engenders suspicion in those who fear government intrusion into family matters, public education could teach the safety and efficacy of the virus, without undermining an abstinence message. This proposal, which combines elements of the microbial, behavioral, and ecological models, would allow all participants to pursue their goals, without sacrificing public health results or community values. The public health community need not abandon the goal of an HPV vaccine mandate forever. However, for the moment, it does more harm than good.

#### CONCLUSION

The Virginia mandate is an ineffective means by which to gain broader coverage of the HPV vaccine. Though public health professionals have the law on their side, they do not have the support of the voting public or state legislatures. Virginia should consider a different way forward, toward a pragmatic solution that does more to stop the number two cancer killer of women worldwide.